Rest Home

Registered Nurse, RN C

Pharmacist, Ms G

Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 13HDC01720)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mrs A, aged 77 years, was suffering from dementia. On 18 Month1[1] 2013, she was admitted to a semi-secure aged care facility (Rest Home 2) from a less secure facility (Rest Home 1), owing to her dementia and wandering.

2. On 21 Month1, pharmacist Ms G prepared Mrs A's medications (blister packs and loose medications) at a pharmacy (the Pharmacy). Ms G incorrectly dispensed four times the prescribed dose of risperidone. Although the Pharmacy had five dispensary staff members on duty that day, Ms G did not get anyone to check her work, and did not notice the incorrect dose. Ms G had made a number of dispensing errors prior to this incident.

3. When the medication arrived at Rest Home 2, medication reconciliation was not undertaken. Between 22 Month1 and 31 Month1, Mrs A was administered the incorrect dose of risperidone.

4. During this time, Mrs A continued to wander into other residents' rooms, was noted to be very sleepy, and was sometimes unresponsive. Her vital signs were not checked, and no clinical assessments (apart from at admission) are recorded. Nurse Manager RN C felt that her drowsiness was caused by a urinary tract infection (UTI) and the antibiotics she was taking for that.

5. There are instances where Mrs A was not given her regular medications but the reason is not documented. At times, medication was given but not documented. Antibiotics were commenced for Mrs A's suspected UTI, but there was a gap of two days before a second dose was administered.

6. On 31 Month1, the risperidone dispensing error was discovered and corrected. On 6 Month2, Mrs A was transferred to the public hospital where, sadly, she died several weeks later.

Findings

Pharmacist Ms G

7. Pharmacist Ms G selected the incorrect medication dose and failed to check the medication against the prescription. Accordingly, Ms G did not provide services that complied with professional standards and breached Right 4(2)[2] of the Code of Health and Disability Services Consumers' Rights (the Code).

8. Adverse comment is made about Ms G's management of the dispensing error once she was notified of it.

The Pharmacy

9. The Pharmacy did not respond adequately to the risk Ms G posed to consumers as a result of her repeated dispensing errors. By failing to take appropriate steps to prevent

[1] Relevant months are referred to as Month1 and Month2 to protect privacy.
[2] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

further dispensing errors, the Pharmacy placed Mrs A at risk of harm. Accordingly, the Pharmacy breached Right 4(4)[3] of the Code.

Rest Home 2

10. Rest Home 2 had the ultimate responsibility to ensure that Mrs A received care that was of an appropriate standard and complied with the Code. There were a number of concerns with the care provided to Mrs A at Rest Home 2, including staff reliance on the transfer documentation from Rest Home 1, as well as poor medication management, medication reconciliation, and documentation. Furthermore, inadequate staffing, in particular insufficient registered nurse hours, contributed to the poor care provided to Mrs A. Accordingly, Rest Home 2 failed to provide Mrs A with services with reasonable care and skill, and breached Right 4(1)[4] of the Code.

11. Adverse comment is made about the failure to undertake an appropriate assessment of Mrs A's competence, meaning that staff were not in a position to obtain appropriate informed consent for her care and treatment.

RN C

12. RN C was Nurse Manager/Registered Nurse and failed to ensure that staff at Rest Home 2 provided adequate care and treatment to Mrs A. RN C failed to maintain adequate care planning as Mrs A's condition changed and her drowsiness increased. He failed to react appropriately to changes in Mrs A's condition, and did not assess her or monitor her vital signs. RN C did not ensure that appropriate documentation was maintained by Rest Home 2 staff, or that medications were being administered safely in accordance with Rest Home 2's medication policy. Overall, RN C failed to provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Ms D

13. Adverse comment is made about Operational Manager Ms D's record-keeping.

Complaint and investigation

14. The Commissioner received a complaint from Mrs B about the services provided to her mother, Mrs A, at Rest Home 2. The following issues were identified for investigation:

- *The appropriateness of the care provided by pharmacist Ms G to Mrs A in Month1 2013.*
- *The appropriateness of the care provided by the Pharmacy to Mrs A in Month1 2013.*

[3] Right 4(4) states: "Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer."

[4] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

- *The appropriateness of the care provided by Rest Home 2 to Mrs A in Month1 and Month2 2013.*

15. On 12 November 2014, the investigation was extended to include:

- *The appropriateness of the care provided by RN C to Mrs A in Month1 and Month2 2013.*

16. This report is the opinion of Rose Wall, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

17. The parties directly involved in the investigation were:

Mrs A (dec)	Consumer
Mrs B	Complainant
Rest Home 2	Provider
RN C	Nurse Manager/Registered Nurse
Ms D	Operational Manager
Ms E	Care assistant
Ms F	Care assistant
Ms G	Pharmacist
The Pharmacy	Provider

18. Information was also obtained from:

Ms H	Nurse Coordinator, Mental Health Services for Older People, the public hospital
Ms I	Care assistant

Also mentioned in this report:

Rest Home 1	
Dr J	General practitioner
Dr K	Locum GP
Mr L	Pharmacy manager

19. Information from the Coroner was also reviewed.

20. Independent expert advice was obtained from pharmacist Julie Kilkelly (**Appendix B**) and registered nurse Tanya Bish (**Appendix A**).

Information gathered during investigation

Background

Mrs A

21. Mrs A, aged 77 years, had a medical history that included dementia, arthritis, GORD,[5] hypertension, and depression. She resided at Rest Home 1. On 18 Month1 2013, Mrs A was transferred to Rest Home 2 so that she could be in more secure premises in light of her dementia and wandering. No further NASC[6] assessment was arranged at this time. Mrs A had appointed her daughter, Mrs B, as her enduring power of attorney (EPOA) with respect to her personal care and welfare. Rest Home 2 had a copy of the EPOA on file, but, when asked, advised that they had "no documentation to show that this had been medically activated".

Rest Home 2

22. Rest Home 2 is an aged care provider that is semi-secure in that it has a locked gate to prevent wandering from the facility. Rest Home 2 can cater for 34 residents and, at the time of Mrs A's stay, there were 28 residents. Rest Home 2 is registered to provide rest home level care, but does not have a contract to provide dementia care.

23. The New Zealand Handbook "Indicators for Safe Aged-care and Dementia-care for Consumers"[7] recommends two hours of registered nurse input and 12 hours of healthcare assistant input per week per consumer. At the time of these events, Rest Home 2 employed one full-time registered nurse (RN) at Rest Home 2, Nurse Manager RN C, with emergency on-call cover shared by the Nurse Manager and the Operational Manager, Ms D.

24. RN C began working at Rest Home 2 in 2009. RN C's job description stated that his duties included developing nursing care plans to deliver a comprehensive and consistent pattern of care, monitoring staff completion of nursing documentation "to ensure that all documentation [met] legislative requirements and best practice guidelines", and promoting safe practice among all staff. He was also responsible to "[ensure] that all medications are administered safely" in accordance with Rest Home 2's medication policies.

25. The Operational Manager, Ms D, began working at Rest Home 2 in 2011. Her job description stated that her responsibilities included implementing a quality system compliant with the Health and Disability Sector Standards, and implementing an overall Quality Improvement Plan. Although she is a trained nurse, Ms D told HDC that she does not have an annual practising certificate and, if there were any clinical issues, she would call RN C.

26. Rest Home 2 also employs care assistants who are responsible for delivering care to residents.

[5] Gastro-oesophageal reflux disease.
[6] Needs assessment and service coordination.
[7] Standards New Zealand (2005) Standard SNZ HB 8163:2005 (107219).

Transfer Summary

27. The Transfer Summary from Rest Home 1 notes that Mrs A was "very confused". She was noted to be mobilising independently without mobility aids, was incontinent, and required a jumpsuit to prevent her removing her incontinence pads. The Transfer Summary did not list Mrs A's medications and ongoing support needs, and no other documentation accompanied the transfer.

28. The Transfer Summary also records that Mrs A had "NKA" (nil known allergies). In contrast, correspondence from the public hospital records that Mrs A had several allergies, including erythromycin.[8] Rest Home 2 advised HDC that "in this instance we accepted the information provided from [Rest Home 1] on their transfer form that indicated there were no known allergies; discussion with the Nurse Manager at [Rest Home 1] did not indicate any known allergies and [the] Medication Standing Order[9] form received from [Rest Home 1] had no notification of any allergies".[10]

29. RN C said that Mrs A's daughter confirmed the medications taken by her mother at the time of her admission into Rest Home 2, and made no reference to any known medication allergy. Rest Home 2 told HDC that information about allergies is normally obtained from the general practitioner (GP), from any previous clinical records it can access, and from discussion with residents or relatives. However, on this occasion, Rest Home 2 did not ask Mrs A's GP, Dr J, whether Mrs A had any allergies. RN C told HDC that he believed everything possible was done to determine Mrs A's allergy status on her admission to Rest Home 2.

18–20 Month1 2013

Admission to Rest Home 2

30. On Friday 18 Month1, Mrs A was admitted to Rest Home 2. The progress note records that the reason for her transfer was "dementia + wandering which has required a semi secure environment".

31. Rest Home 2 used short-term care plans for the first three weeks after a permanent resident's admission, as well as for short stay residents. That day (18 Month1), RN C carried out an initial care assessment and drafted a short-term care plan (the Care Plan) to guide care of Mrs A prior to completion of a full care plan. The Care Plan documented nil known allergies. Other assessments were completed that day by various staff (healthcare assessment, manual handling profile, falls risk, continence, pressure area, mini mental state examination, mood scale for depression). The mini mental state examination revealed a score of 0/30, indicating that Mrs A had severe cognitive impairment. The healthcare assessment indicated that Mrs A was unable to communicate. The mini nutritional assessment form is blank.

[8] An antibiotic used to treat bacterial infections.

[9] A set of written instructions from a registered medical practitioner to other persons to permit the supply or administration of medicines or specified controlled drugs without a prescription, and to provide medical treatment.

[10] Rest Home 2 provided HDC with the transfer summary, but not the Medication Standing Order form from Rest Home 1.

Medication Policy

32. Rest Home 2's medication policy (the Medication Policy) stated:

> "[S]hort stay residents will have a Short Stay Medication Record filled out and signed by their prime caregivers (or the RN on duty if prime care giver is not present), upon or before admission. This provides written authority for care staff to administer medication on behalf of the usual caregiver — in the absence of any orders to the contrary by the resident's GP. This form can be used on admission in the absence of a completed medication profile."

33. The Medication Policy states that "no new care staff will give any medication to any resident without completing the Staff Medication Competency Monitoring Record". RN C told HDC that medications were administered by care assistants. Rest Home 2 told HDC that, at the time of Mrs A's stay, care assistants accompanied the registered nurse on three medication rounds prior to administering medication themselves.

34. The Medication Policy requires the following checks to be carried out as part of medication administration: check the unit dose when getting the medicine from storage; and check the contents of the unit dose pack or medicine label with the resident's medicine order.

Medication

35. A medication profile had not yet been completed by Mrs A's GP, so on 18 Month1, RN C filled out a Short Stay Medication Record for Mrs A, which listed her current medications. The Short Stay Medication Record was not approved by Mrs A's GP.

36. The Short Stay Medication Record states: "In the absence of instructions from [Dr J] (or locum in case of emergency) the signature of the full time caregiver constitutes our authority to administer these medications according to the caregiver's instructions." The medications listed are metoprolol, Aspirin EC, dothiepin HCl, omeprazole, bezafibrate, allopurinol, lorazepam and risperidone. The PRN[11] medications listed are risperidone and lorazepam.

37. Despite Mrs B not being her mother's full-time caregiver at the time of her transfer to Rest Home 2, the Short Stay Medication Record states under the heading "Name of Full time caregiver" the name "[Mrs B]", and has a space for the caregiver to sign authorising the administration of Mrs A's medications. However, neither Mrs A nor Mrs B had signed it. RN C told HDC that, for a number of reasons, a signature is not obtained routinely. However, the Short Stay Medication Record was signed by RN C.

38. The Short Stay Medication Record included lorazepam[12] 1mg tablets (half a tablet at noon and half a tablet extra up to three times daily when required for agitation) and risperidone[13] 0.5mg tablets (one tablet three times a day and one tablet extra when required for agitation).

[11] PRN medication is prescribed for times when it is seen as required.
[12] A medication used to treat anxiety disorders. Lorazepam can cause sleepiness.
[13] An antipsychotic medication. Risperidone can cause sleepiness.

39. Rest Home 2 uses Medication Administration Signing Sheets (the Signing Sheet) for residents, which have a space for the name, dose and instructions for each medication. For the period 18 to 20 Month1, the Signing Sheet for Mrs A states: "[A]s per short term Med. Record."

40. On 18, 19 and 20 Month1, RN C wrote on the Handover Sheet[14] (which provided information for staff on the following shift) that Mrs A "may also have Rivotril drops".[15] Rivotril drops had not been prescribed for Mrs A. On 19 Month1, care assistant Ms I gave Mrs A PRN lorazepam at 4pm, and PRN Rivotril drops at 7.30pm.

41. RN C said that the Rivotril drops were administered in accordance with standing orders, during busy shifts when staff levels were reduced to two care assistants. He also said that the decision to administer Rivotril drops was based on considerations of Mrs A's safety and dignity. Rest Home 2 provided HDC with several general standing orders signed by various GPs that authorised staff to "at times administer" Rivotril drops ("2–3 drops given for aggression/sedation") to Rest Home 2 residents. However, there was no standing order signed by Mrs A's GP.

21–30 Month1

Prescribing

42. On Monday 21 Month1, Dr K (a locum) reviewed Mrs A, as a newly admitted resident of Rest Home 2, and prescribed a number of medications for her, including risperidone 0.5mg (one tablet three times daily as well as one tablet as required for agitation), and lorazepam 1mg (half a tablet up to three times daily for agitation). She also completed a medication profile for Mrs A which lists her regular and PRN medications and has Dr K's signature against each medication.

43. Dr K noted that RN C had requested that Rivotril drops be prescribed in lieu of lorazepam because drops would be easier to administer if required when Mrs A was agitated. Dr K did not prescribe Rivotril drops in lieu of lorazepam, but she left a note for Mrs A's regular GP to consider this, recording that "[Mrs A was] already on regular lorazepam, might get a bit too much overlap having 2 types of benzos as well as risperidone?".

The Pharmacy

44. The Pharmacy provides pharmacy services to several rest homes including Rest Home 2. The Pharmacy has three full-time pharmacists, two part-time pharmacists, one intern, and one technician.

45. On 21 Month1, the Pharmacy received Mrs A's prescription by fax, but not the medication profile. That day there were five dispensary staff working at the Pharmacy (including one technician). Mrs A's medications were to be dispensed in a blister pack.[16]

[14] The handover sheet records information being passed to the staff on a new shift.
[15] Rivotril drops are oral drops that contain clonazepam, a sedative.
[16] Blister packs contain a person's regular daily tablets or capsules packed and sealed into a ready-to-use separate blister for each period, and usually contain one week's medication.

Policies

46. The Pharmacy's "Prescription Assessment and Clinical Check SOP" (standard operating procedure) states: "Before any label preparation and dispensing occurs, a pharmacist should complete a clinical check on the prescription," and this includes assessment for safety and clinical appropriateness.

47. The "Dispensing Medico Packs[17] SOP" requires that the medication profile is printed and cross-checked against the authorised record (the prescription). The SOP also states that once the medications are assembled for the blister pack, a "pharmacist or second dispensary staff member" is to sign off the correct medications against the medication chart or prescription.

48. The "Accuracy Checking SOP" states that labels and dispensed medications must be checked against the original prescription, self-checking is not recommended, and, whenever possible, the check should be done by a second person. The Pharmacy also has a "Dispensing errors" SOP, ensuring that the correct procedures are followed in the event of a dispensing error.

Ms G

49. On 21 Month1, pharmacist Ms G was responsible for dispensing the blister pack for Mrs A. Ms G has been a registered pharmacist in New Zealand since the mid 90s. She was employed at the Pharmacy in 2009, and started work in the "rest home and blister packing area" a few months later.

50. Ms G does not recall a formal orientation or training process when her employment with the Pharmacy began, but she said she was shown where the SOPs were kept, and that she was familiar with them.

51. The Pharmacy manager Mr L told HDC that he "spent time one on one with [Ms G] going through our relevant SOPs at [her orientation] and how we have been carrying out those tasks". He also said that Ms G had experience from her previous job, which enabled her to take over the responsibility for blister packing readily.

52. At that stage, the Pharmacy had not received Mrs A's medication profile,[18] because she was a new patient and Rest Home 2 had not faxed it to the pharmacy. Ms G stated that a faxed prescription arrived for Mrs A, and it was not unusual to not yet have a medication profile for a new or respite patient.

53. On 21 Month1, Ms G erroneously entered "2mg risperidone" into the Pharmacy's computerised dispensing programme and generated labels. Although she stated that she would have selected the medicine from the shelves using Mrs A's prescription (which stated 0.5mg), rather than the labels, she selected 2mg risperidone from the shelves.

[17] Blister packs are referred to in the Pharmacy's policies as Medico Paks, which is a brand name.
[18] Ms G told HDC that the Pharmacy received the Rest Home 2 medication profile for Mrs A (signed by the GP) after 29 Month1.

54. Ms G then created and printed a medication chart and filled blister packs following the incorrect medication chart. She then checked and counted the tablets in each blister pack against the incorrect labels and sealed the blister pack.

55. Ms G told HDC that she "erroneously selected risperidone 2mg and then continued to fail to recognise [her] mistake". She said that the error (the dispensing error) was carried over to the medication chart, the selection of the medication for the blister pack, and the Signing Sheet. The Signing Sheet is a medication administration signing sheet provided with the blister packs, which is created by the pharmacist and notes the medicines to be administered, along with the directions. The Signing Sheet has spaces for the person administering the medications to initial, indicating whether the medication has been given at each specified time. Ms G said that the number after the description of the medication (28)[19] may have contributed to the dispensing error.

56. Ms G stated that, although a technician was in the dispensary, she "completed all the tasks without another staff member checking or being involved in the process". She said that the processing of a blister pack as part of the weekly cycle involves two to three staff members, but on Mondays when the intern was not there she would "do the whole process".

57. Ms G said that the Pharmacy's dispensing programme would have flagged "sedation" as a warning, owing to the relatively high dose, and noted: "I regret that I did not heed this and the relatively high dose of risperidone."

Arrival of medication at Rest Home 2

58. Mrs A's medication arrived at Rest Home 2 in the evening of 21 Month1, and was not checked by RN C as he had left for the day. With the medication was the Signing Sheet provided by the Pharmacy, which recorded the incorrect dose (2mg).

59. Mrs A's Rest Home 2 medication profile completed by Dr K on 21 Month1 showed the correct dose of risperidone (0.5mg).

60. Rest Home 2 told HDC that normally medications dispensed by the Pharmacy were checked and signed off by the Nurse Manager/RN after completing medication reconciliation. Medications received after hours were signed in by the senior care assistant on duty with allocated responsibility for medication management, but this process did not include a full medication reconciliation. On this occasion, care assistant Ms E signed in the medications.[20]

61. RN C said that the record of receipt of medication after hours was not followed up by the registered nurse unless staff reported that a medication was unavailable to administer. RN C told HDC that he was oriented to this process when he started at Rest Home 2.

[19] This number usually means either the number of tablets dispensed, or the number of days the medication is dispensed for.

[20] Ms E completed her medication competency in July 2013. The Medicines Care Guides for Residential Aged Care (2011) states that medicines must be checked against the medicine chart on arrival at the facility by a staff member who has demonstrated medicines management safety competency.

Medication administration

62. The Signing Sheet for the period 21 Month1 to 3 Month2 prepared by Ms G includes a typed instruction to administer "risperidone 2mg". RN C told HDC that the care assistants were instructed to use the medication profile when administering medication (not the Signing Sheet). As noted above, the medication profile was correct, but the Signing Sheet was incorrect.

63. The Handover Sheet for 21 Month1 includes a handwritten entry "Rivotril", but this is crossed out, leaving: "Lorazepam — at settling. [R]isperidone — at settling." However, at 10pm, care assistant Ms E gave Mrs A PRN lorazepam and PRN Rivotril drops. Ms E told HDC that this was because Mrs A was "particularly aggressive on duty that night".

64. On 22 Month1, RN C wrote on the Handover Sheet: "Use risperidone PRN for behaviour problems — in trolley. GP does not want Rivotril used." This entry is repeated from 23 Month1 to 28 Month1.

65. RN C stated:

> "I must take responsibility for the fact that both Lorazepam and Rivotril have been given simultaneously. A possible scenario/explanation for the carers' actions here could be that Lorazepam is known to them as a 'sleeping pill' and probably used in an attempt to settle [Mrs A]."

66. From 22 Month1 until 31 Month1 Mrs A was given risperidone (2mg), which was four times the strength she was prescribed. According to Rest Home 2's medication profile, she should have received three tablets daily and one tablet for agitation, as required. There are occasions where there is no record of Mrs A receiving her regular medications, but there is no reason for that provided on the Signing Sheet.

Drowsiness and wandering

67. Between 22 and 31 Month1 there are numerous records in Mrs A's progress notes of her being "very sleepy".

68. At 2pm on 22 Month1, the progress notes read: "[RN C] came to help wake her + put her on shower chair as she was sleeping in the lounge, during shower she was very quiet + unresponsive." No clinical assessment or vital signs are recorded in the progress notes on this date. RN C told HDC that observations were taken as routine information, which was required by both Mrs A's GP and Mental Health Services for Older Persons (MHSOP), but this information was sometimes not documented owing to work pressures.

69. On 22 Month1 during the evening shift Mrs A was noted to be "very sleepy". She was given PRN lorazepam at 8.30pm.

70. On 23 Month1, the progress notes record that Mrs A had been wandering in and out of rooms during the morning and afternoon/evening. She was given PRN risperidone at 9pm, in addition to the three tablets in her regular medication.

71. On 24 Month1, the progress notes read: "[U]rine smell offensive. Need urine spec[imen] in the morning." There are two incident reports recording Mrs A wandering into other residents' rooms. Mrs A was given PRN risperidone at 8.30pm in addition to her regular medication. Mrs B said that on 24 Month1, she met with the owner of Rest Home 2 and Ms D, and "received the distinct impression … that my mother would possibly need a higher level of care than they could provide. I advised them that I would continue looking at other possible rest homes, more suitable to her needs."

72. At 7am on 25 Month1, the progress notes record that Mrs A was "sleeping during checks cannot rouse her …".

73. That day, RN C faxed nurse coordinator Ms H at MHSOP, the public hospital. RN C had concerns about Mrs A's behaviour, and requested Ms H's input in relation to possible reassessment of Mrs A, and the possibility of transferring her to a "more secure/purposeful facility".

Suspected UTI[21]

74. RN C told HDC that during her stay at Rest Home 2, Mrs A was wandering into other residents' rooms and voiding in them. He said: "It was the fact that this behaviour was foreign to [Mrs B] and to [Rest Home 1], coupled with the highly offensive odour of her urine that formed my diagnosis of UTI." RN C told HDC that Mrs A showed no physical signs of dehydration, was consuming full meals, and was maintaining an adequate fluid intake.

75. RN C faxed Dr J to request antibiotics for a suspected UTI, as he was unable to collect a urine sample from Mrs A, given her incontinence. The medication records show that a five-day course of antibiotics (trimethoprim, once daily) was commenced, but there is no prescription on file. The Signing Sheet shows that doses of trimethoprim were given between 25 and 30 Month1, but no doses were given on 26 and 27 Month1.

76. On 26 Month1, RN C completed a short-term care plan for Mrs A's suspected UTI, which included monitoring her behaviour, ensuring adequate hydration, and managing nausea and diarrhoea. No fluid balance chart was commenced until 31 Month1.

77. RN C said that Ms H told him that the course of antibiotics should be administered to rule out possible delirium as the underlying cause of Mrs A's changing behaviour, and to contact MHSOP again at a later date. RN C stated:

> "I freely admit that it was a blind determination to follow this advice and see the full course of the antibiotic administered prior to considering any other possibilities that prolonged the administration of the [risperidone]."

78. RN C said that he became focused on Mrs A's suspected UTI, and attributed Mrs A's drowsiness to symptoms of infection and the antibiotics. He said that he regrets that

[21] UTI is a urinary tract infection.

he did not "fully use [his] experience to implement a wider investigation into other possible causes for [Mrs A's] sedation".

28–30 Month1

79. On 28 Month1, the progress notes record that "[Mrs A] was really good", and that she was assisted to bed and "settled well". Mrs A was given PRN lorazepam at 8.30pm.

80. At 1pm on 29 Month1, the progress notes read: "[Mrs A] was very sleepy + tired, unresponsive sometimes." The notes also record that both morning and lunchtime medications were withheld, but there is no further documentation in relation to this. At 6.30pm, Mrs A was given PRN lorazepam. There are no progress notes for the afternoon or evening shift.

81. On 30 Month1, Ms D told Mrs B that she had spoken to Ms H, who had advised that MHSOP had decided to cancel Mrs A's assessment, as Mrs A had improved. Mrs B was not happy with this decision, and telephoned Ms H to express her concerns.

82. During the evening shift on 30 Month1, the progress notes read: "[Mrs A] remained sleeping in the lounge this entire shift, barely rousable."

Discovery of medication error — 31 Month1 2013

83. On 31 Month1, Ms H reviewed Mrs A. Ms H and RN C discovered that Mrs A was being given 2mg risperidone, rather than 0.5mg as prescribed. Ms H recorded:

> "[Mrs A] had no medications yesterday morning as she was asleep. Staff state [Mrs A] to have had minimal fluid or food intake as sleepy — over the past 24 hrs. Care staff express the drowsiness to be due to the 3 day course of Trimethoprim as the staff member reports she gets very sleepy on antibiotics. [Mrs A] not rousable though flinches when staff moved her legs back onto the bed.
>
> … [Mrs A] presents as being oversedated.
>
> [Mrs A] has been given 4 times the prescribed dose and staff have made use of the prn doses x 6 though only signed for 2 doses."

84. Dr K was advised of the dispensing error and recorded that Mrs A "apparently was woken up this am to give her morning risperidone (2mg) even though deemed too sleepy to have rest of meds". Dr K gave RN C instructions by fax. Her note states:

> "Please could you check [Mrs A's] BP/heart rate and if systolic BP <100 and/or heart rate >100 then consider sending her off to ED for assessment (if daughter [Mrs B] agreeable for this) … I will ask the chemist to remove risperidone for the rest of the day and can restart on 0.5mg tomorrow. PRN risperidone or lorazepam should only be given if she is agitated and also alert/not sedated. If she is really sedated then I would withhold all her meds."

85. Dr K advised Mrs B and the Pharmacy of the dispensing error.

86. Ms D told HDC that all of Mrs A's medications were withheld for 24 hours. Mrs A was not taken to ED for assessment.

1–6 Month2

87. On 1 Month2, a GP reviewed Mrs A and recorded that she was "rousable and more alert today but still far from her usual self".

88. On 1 Month2, care assistant Ms F added doses of ibuprofen,[22] prednisone,[23] and Paracare[24] to Mrs A's medication profile in error. There is no prescription for these medications. This was contrary to the medication policy, which states:

> "The senior person on duty must ask the doctor to clarify anything he or she cannot read or understand. When a profile becomes untidy or needs to be re-written a new profile can be ordered from the pharmacy prior to the next GP visit however, the prescribing practitioner must write in the dose, date and the frequency, and sign off all drugs again. All changes/additions or deletions to the profiles shall be faxed to the pharmacy to ensure their information is up to date."

89. RN C told HDC that a GP had prescribed Mrs A analgesia and prednisone, but he did not know where the faxed prescription was.

90. On 3 Month2, "pressure marks on the sacrum" is recorded in the progress notes and, on 4 Month2, Mrs A was given a pressure relieving cushion. Mrs B told HDC that she was not aware of the pressure marks until Mrs A was transferred to the public hospital on 6 Month2.

91. On 4 Month2, Mrs A's progress notes record that she was "not bearing weight properly. Unsteady on feet." RN C faxed Dr J, stating that Mrs A was "no longer mobilising independently". However, Mrs A's Care Plan was not updated to reflect this.

92. Mrs A was assessed by the registrar from MHSOP after discontinuation of the risperidone, and the registrar noted the need to fully explore causes for Mrs A's drowsiness, including acute infection and hypoactive delirium. Ms D told HDC that a blood test was ordered, as Mrs A was still not fully responsive, and that the results were indicative of a risperidone overdose.

93. At 2.30am on 5 Month2, staff found Mrs A "face down on the floor". The progress notes record that a "visual check found nothing", but that her right shoulder was tender to touch. No incident form was completed. RN C said that he should have amended Mrs A's Care Plan to show her increased falls risk following her decline in mobility, but he did not do so.

[22] Ibuprofen is an anti-inflammatory medication.
[23] Prednisone is an anti-inflammatory and immunosuppressant medication.
[24] Paracare is a pain relief medication.

94. That day, RN C completed a Wound Assessment and Management Plan, noting a "small pressure sore from prolonged period of inactivity/sitting", that pressure relief cushions were being used, and that dressings were commenced on alternate days.

95. Mrs A's progress notes contain no record of her vital signs having been measured during her time at Rest Home 2 except for those recorded by the GP on 21 Month1.

96. Mrs B told HDC that "in just over 2 weeks [Mrs A had] gone from a semi independent person to a highly dependent one".

97. On 6 Month2, at the request of her family, Mrs A was transferred from Rest Home 2 to the public hospital. The discharge summary states that Mrs A was "admitted to MHSOP inpatient care following change of rest homes and inadvertent overdose of Risperidone; becoming very sedated and developing a large sacral pressure area cavity". Mrs A was placed on a palliative care management pathway. She was initially very restless, then she stopped eating and drinking.

98. Sadly, Mrs A died a few weeks later.

Further information — the Pharmacy

99. Mr L provided information to HDC showing that Ms G had made a number of dispensing errors prior to these events, as there had been eight errors in blister packs dispensed by Ms G over the period of a year. Mr L told HDC that in response to the errors, he discussed with Ms G her failure to comply with SOPs and, at a staff meeting prior to these events, when errors were specifically discussed, she was given a copy of the relevant SOPs for dispensing blister packs. The staff meeting records reveal that SOPs were discussed regularly at staff meetings. There is no evidence that any performance management process was undertaken after any of the dispensing errors.

Further information — RN C

100. RN C accepted that his lack of written records, including observations, was a breach of correct documentation procedure, but said that this was "due to work pressures on [his] time; especially during episodes of decline in an individual's health status". He stated that he had to choose between delivering care and writing about it, and said that he had told Ms D on several occasions about his workload concerns, but did not notify management of his concerns in writing.

101. RN C said that he was in an unsupported role and had administration and management obligations to meet on top of his clinical role. He stated that he had performed his role without difficulty under the previous owner, who was an enrolled nurse and who took a more active clinical role. He said that his managerial input increased under the new management, as Ms D did not have a practising certificate and so was unable to be clinically supportive. In response to the provisional opinion, RN C also stated that he does not believe that the report "[a]ddresses the full pressures and scope of my role during my employment with [Rest Home 2]". He resigned from Rest Home 2 in October 2014. RN C stated that he is "deeply remorseful" that he did not investigate other causes for Mrs A's drowsiness.

Actions taken following incident

Rest Home 2

102. Ms D told HDC that, while she was preparing a response to this complaint for Rest Home 2, she noticed Ms F's error on Mrs A's medication profile, and discussed it with Ms F. Ms D crossed out the additions made by Ms F, and wrote "error" alongside her initials, but did not record the date of the amendment. She said that as it was four months after the incident, she did not complete an incident report.

103. Rest Home 2 advised that it has made the following changes since this incident:

- The Medication Policy was revised to include clear directives on medication reconciliation.
- An after-hours medication policy was implemented, requiring that medication is checked against the resident's medication profile.
- A medication reconciliation sign-in sheet was implemented.
- An after-hours medication procedure questionnaire was added to the Medication Policy questionnaire given to the care assistants.
- All staff were instructed on these changes and the importance of completing medication reconciliation.
- All care assistants are required to complete a minimum of five medication rounds with a registered nurse as part of their initial medication competency.
- A second registered nurse has been appointed to assist the Nurse Manager.
- Rivotril drops have been removed from the Standing Order Forms.
- Ongoing training on medications has been provided, including the requirement to sign for all medications and to indicate the reason if medication is not given.
- It has undertaken audits, including internal spot audits, of medication signing sheets.
- An audit of medication management has been undertaken by an external nurse manager.
- A simplified food and fluid chart has been introduced, which allows circling of appropriate volumes to aid the monitoring of fluid and food tolerated.
- All new staff are given an orientation pack.

The Pharmacy

104. All pharmacists at the Pharmacy have been made aware of the dispensing error, and the importance of following the SOPs has been highlighted. The Pharmacy advised that it has made the following changes:

- The retail staff have been asked to minimise interruptions to pharmacists during the dispensing and checking process.
- The pharmacy stamp has been changed to include initialling boxes for the inputter, the dispenser, and the checker.
- A further new stamp has been introduced to identify the people involved in each of the dispensing steps in blister pack prescriptions.
- The Dispensing Medico Packs SOP was amended to include:
    - A clinical accuracy check (the foil, header card and dose pack chart are printed and cross checked against the new prescription or latest medication chart).

- A second pharmacist checking the accuracy of data entry against the prescription or the medicine chart.
- A statement that "self-checking is not recommended".
- A requirement that the blister pack is sealed prior to the final accuracy check.
- A note being attached to the blister pack if fridge items or other non-packed items are to be given out with the blister pack.

105. In response to my provisional opinion, the Pharmacy stated that it had an obligation to work through Ms G's competence issues internally, and was doing that. Following the incident with Mrs A, a performance management process in relation to Ms G was commenced, and Ms G is no longer employed by the Pharmacy. However, the Pharmacy accepted that it could have notified the Pharmacy Council of concerns regarding Ms G's competence or commenced "formal employment processes" sooner. It noted that it believes its approach to managing Ms G was consistent with good employment practice, and the steps taken "were within the range of steps that a reasonable employer would take".

Ms G

106. On 8 Month2, Ms G completed an incident report and apologised in writing to Rest Home 2 and to Mrs A. To explain the delay in completing the incident report, Ms G told HDC that she had assumed that another staff member had logged the incident.

107. Ms G advised that she has made the following changes to her practice:

- She has all her work checked, and self-checking is now "rarely done".
- She practises mindfulness to aid calm focus while checking and working.
- She has requested to go on a checking course.
- She has stopped drinking coffee during her breaks.
- She adds tablet descriptors to blister pack labels.

DHB involvement

108. The DHB investigated the incident, and the Ministry of Health (HealthCERT) conducted a surveillance audit of Rest Home 2. The DHB was satisfied that Rest Home 2 implemented strategies to mitigate the likelihood of dispensing errors not being picked up in the future.

Relevant standards

109. The Medicine Care Guides for Residential Aged Care 2011 states: "Medicines must be checked against the medicine chart on arrival at the facility by a staff member who has demonstrated medicines management safety competency."

110. The NZS 8134.1:2008 Health and Disability Services (Core) Standards require that providers ensure:

"(a) Consumers receive safe services of an appropriate standard that complies with consumer rights legislation;

(b) Consumers receive timely services which are planned, coordinated, and delivered in an appropriate manner;

(c) Services are managed in a safe, efficient, and effective manner which complies with legislation; and

(d) Services are provided in a clean, safe environment which is appropriate for the needs of the consumer."

111. The Nursing Council of New Zealand Competencies for Registered Nurses (December 2007, reprinted May 2012) provide:

"**Competency 1.1**
Accepts responsibility for ensuring that his/her nursing practice and conduct meet the standards of the professional, ethical and relevant legislated requirements.
…

Competency 1.3
Demonstrates accountability for directing, monitoring and evaluating nursing care that is provided by enrolled nurses and others.

Competency 1.4
Promotes an environment that enables health consumer safety, independence, quality of life, and health.
…

Competency 2.3
Ensures documentation is accurate and maintains confidentiality of information.
Indicator: Maintains clear, concise, timely, accurate and current health consumer records within a legal and ethical framework."

112. The Pharmacy Council Competence Standards (updated in 2010) include:

"2.3.2 For each medication checks that the dosages and methods of administration are optimal
…

4.1.3 Supports the work of colleagues in the workplace

Works in partnership with colleagues in workplace, if applicable, to ensure safe practice
…

6.2.2 Follows workplace dispensing criteria when dispensing a prescription item"

Opinion: Ms G

Dispensing error — Breach

113. The Pharmacy had a number of standard operating procedures (SOPs) in place to ensure safe dispensing. The Pharmacy Council competence standards require pharmacists to follow workplace dispensing criteria when dispensing a prescription.

114. Ms G was responsible for dispensing the wrong dose of risperidone to Mrs A on 21 Month1. Ms G entered the incorrect dose into the Pharmacy's dispensing programme and generated labels from this. Although she stated that she would have selected the medicine from the shelves using the prescription (which stated the correct dose), not the labels, she selected the incorrect strength of medication from the shelves. Ms G stated that although a technician was in the dispensary, she "completed all the tasks without another staff member checking or being involved in the process".

115. The "Prescription Assessment and Clinical Check SOP" states that "[b]efore any label preparation and dispensing occurs, a pharmacist should complete a clinical check on the prescription", which includes assessing for safety and clinical appropriateness.

116. Ms G acknowledged that the software she was using would have flagged sedation as a warning given the relatively high dose, and that she did not notice the relatively high dose of risperidone.

117. The "Dispensing Medico packs SOP" requires that the medication profile is printed and cross-checked against the prescription. There is no evidence that Ms G completed this check. The SOP also required that, once the medications were assembled for the blister pack, a "pharmacist or second dispensary staff member" sign off the correct medications against the medication chart or prescription. Ms G did not follow this process.

118. The "Accuracy Checking SOP" states that self-checking is not recommended. My expert advisor, pharmacist Julie Kilkelly, advised that in some cases self-checking cannot be avoided, but the staffing levels in the pharmacy that day would have been adequate to allow a second person to check Ms G's data entry and dispensing. Ms Kilkelly advised that it was "a significant error of judgement on [Ms G's] part not to have another person check her work, especially given her past history of errors". I agree.

119. Ms Kilkelly also advised that "not noticing or ignoring warnings about sedation (due to interacting drugs which should make you think again and have a closer look at combinations and dosages) and then choosing to do all steps in the dispensing process herself not only put the patient at risk but also prevented others from complying with their ethical, legal and professional obligations".

120. Checking that the patient is being dispensed the correct dose of medication is a critical part of pharmacy practice and a requirement of the Pharmacy's SOPs. By selecting the incorrect medication, and failing to complete an appropriate clinical check on the prescription, Ms G did not provide services that complied with professional standards and breached Right 4(2) of the Code.

Incident management — Adverse comment

121. The Pharmacy has a "Dispensing errors" SOP ensuring that the correct procedures are followed in the event of a dispensing error. It appears that this has been followed, although there is a concerning gap between Ms G being notified of the error on 31 Month1, and the subsequent paperwork trail, as the incident report is dated 8 Month2. Ms Kilkelly advised that an incident should be recorded immediately following notification and correction of the error. I agree.

122. Ms G told HDC that she had assumed that another staff member had logged the incident. In my view, it was Ms G's responsibility to clarify this with the staff member and ensure that the incident form was completed.

Opinion: The Pharmacy

Standard operating procedures — No breach

123. In the course of this investigation, I have carefully considered the extent to which the dispensing error that occurred is attributable to individual action or inaction by Ms G, as opposed to systems or organisational issues at the Pharmacy. As this Office has previously stated, "a pharmacy has a responsibility to ensure that all pharmacists working in the Pharmacy are appropriately trained and experienced, and aware of the Pharmacy's expectations, including the SOPs".[25] In addition, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for acts or omissions by an employee. Under section 72(5), it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent acts or omissions leading to an employee's breach of the Code.

124. Written SOPs are central to ensuring safe and effective dispensing. Ms Kilkelly reviewed the Pharmacy's SOPs and advised that they are "appropriate, straight forward and practical and constitute good practice procedures". Ms G stated that she was familiar with the Pharmacy's SOPs, and the staff meeting records reveal that SOPs were discussed regularly at these meetings.

125. I am concerned that the SOP refers to the medication profile as a mechanism for checking that the correct medications are being dispensed despite it not always being available. However, in my view, Ms G's dispensing error was an individual clinical error, and cannot be attributed to the system in which she was working. I therefore find that the Pharmacy is not responsible for Ms G's breach of the Code.

Management of risk of harm — Breach

126. Ms G had made at least eight dispensing errors with blister packs at the Pharmacy over a year prior to the incident at the centre of this report.

[25] See Opinion 13HDC00819.

127. In response to her errors, Mr L had a discussion with Ms G about her failure to comply with SOPs, and she was given a copy of the relevant SOPs for dispensing blister packs. In response to the provisional opinion, Mr L noted that he believes that the Pharmacy's approach to managing Ms G was consistent with good employment practice, and the steps taken "were within the range of steps that a reasonable employer would take". Ms Kilkelly advised that, although Mr L took the errors seriously and worked with staff — in particular Ms G — to prevent recurrences, the Pharmacy could have taken more action to address Ms G's repeated failure to follow SOPs.

128. I acknowledge that the Pharmacy had employment procedures to consider. However, patient safety must be the paramount consideration. The Pharmacy was on notice that there were issues with Ms G's performance, and I remain of the view that the Pharmacy's actions were an insufficient response to the risk Ms G's dispensing errors posed to consumers as a result of her multiple errors.

129. By failing to take adequate steps to prevent recurrence of dispensing errors by Ms G, the Pharmacy placed Mrs A at risk of harm. Accordingly, the Pharmacy breached Right 4(4) of the Code.

Other comment

130. I note that Ms Kilkelly provided comment on the changes made by the Pharmacy since the medication error. She advised that the additional check of the data entry in the "Dispensing Medico Packs SOP" seems an unnecessary step, "which is likely to reduce efficiencies while adding little value". She further stated that sealing of the blister pack prior to the final accuracy check is not a safe procedure "if the pack contains too many tablets similar in appearance or alternating dose regimens as, in [her] opinion, it is too hard to distinguish some tablets from others and accurately count tablets when they are jammed in blisters".

131. Ms Kilkelly also advised that the additional data entry check by another dispensary staff member is unnecessary and likely to interrupt dispensary flow and efficiency.

Opinion: Rest Home 2 — Breach

Introduction

132. In accordance with the Code, Rest Home 2 has a responsibility to ensure its residents receive services of an appropriate standard. The New Zealand Health and Disability Sector Standards (NZHDSS) also require that rest homes ensure that the operation of their services is managed in an efficient and effective manner, which ensures the provision of timely and safe services to consumers.[26]

[26] NZS 8134.1.2008 Health and Disability Services (core) Standards.

133. In my view, this is particularly important when providing care to residents with a history of dementia. I find that Rest Home 2 failed in its organisational duty to ensure that Mrs A received services of an appropriate standard, for the reasons set out below.

Medication reconciliation

134. My expert advisor, Tanya Bish, advised that it is accepted good practice that medication dispensed by a community pharmacist for a resident in a residential aged care facility is checked on arrival at the facility. The Medicines Care Guides for Residential Aged Care (2011) recommend that this check is carried out by a staff member who has demonstrated medicines management safety competency.

135. Medications dispensed by the Pharmacy were normally checked and signed off by the Nurse Manager/RN after completing a medication reconciliation. Medications received by Rest Home 2 after hours were signed in by the senior care assistant on duty with allocated responsibility for medication management, but this process did not include a full medication reconciliation. The care assistant was responsible for recording that medications had been received from the pharmacy, but there was no requirement to reconcile them against the medication profile. The registered nurse did not reconcile medication received after hours unless staff reported that a medication was unavailable to administer. In my view, this was a flawed policy. On 21 Month1, Ms E signed in Mrs A's medications.

136. A check against Mrs A's medication profile at that time could have identified the dispensing error. I am concerned that the dispensing error was not picked up by Rest Home 2 staff for nine days. The Medication Policy required a check of the unit dose when getting the medicine from storage, and a check of the contents of the unit dose pack or medicine label with the resident's medication profile. If the Medication Policy had been followed, the unit dose would have been checked against Mrs A's medication profile and earlier identification of the dispensing error would have resulted.

137. Multiple staff failed to carry out these checks, which is indicative of a systems issue at Rest Home 2 for which Rest Home 2 is responsible. The Signing Sheet from 21 Month1 to 3 Month2 includes a typed instruction to administer "risperidone 2mg". Care assistants were instructed to use the medication profile when administering medication (not the Signing Sheet). As the medication profile was correct but the Signing Sheet was incorrect, the failure to follow this instruction was a lost opportunity to detect the error.

Transfer documentation

138. The Transfer Summary from Rest Home 1 was suboptimal in that it did not include medications or the care Mrs A required. In addition, it records that Mrs A had no known allergies. However, clinical notes from the public hospital indicate that Mrs A had several allergies, including an allergy to erythromycin. Rest Home 2 staff relied on the information provided from Rest Home 1 on its transfer form, which indicated that there were no known allergies; the discussion with the Nurse Manager at Rest Home 1, who did not indicate any known allergies; and the Medication Standing Order form received from Rest Home 1, which had no notification of any allergies.

RN C said that Mrs A's daughter confirmed the medications taken by her mother at the time of her admission into Rest Home 2, but made no reference to any known medication allergy.

139. Rest Home 2 told HDC that information about allergies is normally obtained from the resident's GP, from previous clinical records they can access, and from discussion with residents or relatives. On this occasion, Mrs A was very confused, and Rest Home 2 staff did not seek to obtain information about allergies from Mrs A's GP or Mrs B. Ms Bish advised: "The admitting facility has a duty of care to make every attempt to ensure the information they are recording is accurate. This may involve accessing previous medical notes/details."

140. I am critical that neither Mrs B nor Mrs A's GP were asked specifically about allergies. It was unwise for Rest Home 2 staff to assume that a lack of specific reference to allergies on a brief transfer form and the Medication Standing Order form was sufficient.

Medication management

141. I am concerned about several aspects of the medication management for Mrs A. Between Mrs A's admission on 18 Month1 and review by Dr K on 21 Month1, Mrs A was administered medication according to a short-stay medication record, which had not been approved by her GP. Ms Bish advised that this was potentially unsafe practice. She noted:

> "Whilst there are obvious challenges with getting all admissions seen on the day of admission there should be an ability to send a medication chart to the GP for confirmation that the GP is agreeable to the resident receiving those medications until they complete their admission visit on site. Alternatively a medication chart and scripts signed by the transferring GP can be used in the interim if the receiving GP agrees."

142. The incorrect dose of risperidone being administered to Mrs A was not picked up until 31 Month1, when a registered nurse from MHSOP visited Mrs A. Furthermore, on a number of occasions, Rivotril drops were administered to Mrs A without a prescription. Although there were several standing orders, Ms Bish advised that these were not consistent with the Standing Order Guidelines 2012.[27] In addition, Mrs A's GP had not signed the Standing Order, and had indicated on 21 Month1 that Rivotril drops should not be administered to Mrs A.

143. I am also concerned that there are instances where lorazepam or risperidone (prescribed for agitation) were administered when Mrs A was reported to be sleepy or wandering into other residents' rooms. For example, on 22 Month1 she was recorded to be sleepy, on 23 Month1 she was wandering, and on 28 Month1 she was noted to have been really good, yet on each occasion lorazepam or risperidone was administered. In my view, drowsiness or wandering into other residents' rooms does

[27] This guideline outlines the roles and responsibilities of health professionals using standing orders, and those working under standing orders.

not equate to agitation. I note Ms Bish's comment that no behaviour monitoring chart was initiated to monitor behaviours that were causing staff concern.

144. Ms Bish advised that the multiple concerns in relation to medication management suggest systems failures, and that Rest Home 2 has very unsafe practices, which are severe departures from accepted practice. I accept Ms Bish's advice.

Documentation

145. With regard to documentation, there are a number of occasions where the Signing Sheet is incomplete. In places, there is no record indicating whether medication was given and, if not, the reason for this. On 29 Month1, Mrs A's morning and lunchtime medications were withheld but, apart from a note that she was "very sleepy + tired, unresponsive", there is no further documentation in relation to this. Ms Bish is critical that there is no evidence that a clinical assessment was undertaken, or that Mrs A's vital signs were monitored on that date.

146. Mrs A should have been administered trimethoprim each day from the time the course of antibiotics was prescribed, but the administration record does not reflect this, with a gap between the first and second doses of multiple days. There is no documented reason for this omission.

147. There are no prescriptions signed by an authorised prescriber in the medication profiles for ibuprofen, prednisone, Paracare, trimethoprim or subcutaneous fluids. Ms Bish advised that even if they were faxed directly to the pharmacy, a signed order is required to be kept in the clinical file.

148. This Office has frequently emphasised the importance of record-keeping.[28] Baragwanath J indicated in his decision in *Patient A v Nelson–Marlborough District Health Board*[29] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk by a doctor). In my view, this applies to all health professionals, who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted.

149. In my view, the failure to record medications given or, if they are not given, the reasons for that decision, is poor practice, affects continuity of care, and puts residents at real risk of harm. For instance, in the absence of good documentation, Mrs A was as much at risk of being given an overdose as receiving no medication at all from those responsible for her care. Furthermore, no long-term care plan was completed, no records of her vital signs having been measured was completed during her time at Rest Home 2 except for those recorded by the GP on 21 Month1, and no fluid balance chart was commenced until 31 Month1.

[28] Opinion 08HDC10236, available at www.hdc.org.nz.
[29] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV-2003-406-14, 15 March 2005).

Staffing levels

150. Rest Home 2 employed one full-time registered nurse as the Nurse Manager. At the time of Mrs A's stay, there were 28 residents at Rest Home 2. Ms Bish advised that the nursing hours were insufficient. The New Zealand Handbook "Indicators for Safe Aged-care and Dementia-care for Consumers"[30] recommends two hours of registered nurse input and 12 hours of healthcare assistant input per week per consumer. As there were 28 residents at Rest Home 2 at the time of these events, 56 hours of registered nurse input was required each week. RN C was employed for 40 hours each week. Accordingly, there were insufficient registered nurse hours for the number of residents at Rest Home 2.

Conclusion

151. Rest Home 2 had the ultimate responsibility to ensure that Mrs A received care that was of an appropriate standard and complied with the Code. I have a number of concerns with the care provided to Mrs A at Rest Home 2, including staff reliance on the transfer documentation from Rest Home 1, as well as poor medication management, medication reconciliation, and documentation. Furthermore, inadequate staffing, in particular insufficient registered nurse hours, contributed to the poor care provided to Mrs A. Accordingly, Rest Home 2 failed to provide Mrs A with services with reasonable care and skill at Rest Home 2, and breached Right 4(1) of the Code.

Competence assessment and informed consent — Adverse comment

152. Except in limited circumstances, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent (Right 7 of the Code). For consent to be valid, it needs to be freely and competently given. This raises the question of whether Mrs A was competent to make an informed choice and give informed consent to her care and treatment.

153. Right 7(2) of the Code provides that every consumer must be presumed competent unless there are reasonable grounds for believing they are not competent. If a consumer is not competent to consent, consent should be sought from someone legally entitled to consent on that person's behalf (for example, the person holding an activated EPOA).

154. Mrs A had a history of dementia, and was recorded as being confused and agitated. A mini mental state examination revealed that she was severely cognitively impaired. Accordingly, there were reasonable grounds to question her competence to consent to the care and treatment provided at Rest Home 2. Apart from the mini mental state examination, there is no evidence that Rest Home 2 staff formally assessed Mrs A's competence during her stay.

155. Mrs B had provided Rest Home 2 with a copy of the EPOA with respect to Mrs A's personal care and welfare, signed in 2005, but there is no evidence that it was ever activated by way of medical certification of incompetence. In my view, Rest Home 2 had a duty to ensure that Mrs A's competence was formally assessed at Rest Home 2

[30] Standards New Zealand (2005) Standard SNZ HB 8163:2005 (107219).

at admittance, in order to ascertain who was able to provide informed consent to Mrs A's care and treatment.

Opinion: RN C — Breach

Introduction

156. As the Nurse Manager, RN C had overall responsibility for the clinical care provided to residents at Rest Home 2. RN C's job description stated that his duties included developing nursing care plans to deliver a comprehensive and consistent pattern of care, monitoring staff completion of nursing documentation, and promoting safe practice among all staff. In addition, the Nursing Council of New Zealand Competencies for Registered Nurses state that the standard expected of a registered nurse in management is to promote a quality practice environment that supports nurses' abilities to provide safe, effective and ethical nursing practice.

157. As a registered nurse, RN C also had a responsibility to promote an environment that enabled Mrs A's safety, independence, quality of life, and health. He also was required to maintain clear, concise, timely, accurate and current health consumer records. Ms Bish advised that, in a rest home environment, the registered nurse is responsible for assessment, care planning and evaluation, and the direction and delegation of care staff.

Drowsiness and UTI

158. From 22 Month1, staff reported Mrs A's increased sleepiness, although they also reported at times that Mrs A was entering other residents' rooms.

159. On 22 Month1, when a care assistant asked RN C to help wake Mrs A, RN C did not record a clinical assessment or Mrs A's vital signs. Ms Bish advised that as Mrs A's increased sleepiness and entering other residents' rooms had not previously been observed, it would have been prudent for RN C to have conducted and documented an assessment of Mrs A and her vital signs.

160. On 24 Month1, Mrs A was noted to have offensive smelling urine. RN C had difficulty obtaining a sample for laboratory analysis, and faxed Mrs A's GP, suggesting that antibiotics might be necessary. Mrs A's GP did not visit Mrs A, but prescribed an antibiotic for her. Ms Bish advised that there are reasons (other than infection) why a person may have offensive smelling urine, such as dehydration or eating certain foods. She advised that it would have been beneficial to have had more clinical information, such as vital signs and a comprehensive clinical assessment. Ms Bish advised that other possible reasons for the change in Mrs A's behaviour and health status should have been explored.

161. On 29 and 30 Month1, Mrs A was reported to be "sleepy", "unresponsive", and "barely rousable". Ms Bish advised that Mrs A's sleepiness may have been due to a UTI, but again her vital signs and a comprehensive clinical assessment should have

been documented, and other possibilities for her change in behaviour explored. Ms Bish noted that further documented care planning to provide direction on the monitoring of Mrs A's increased drowsiness, vital signs, increased risk of pressure area skin breakdown, and increased falls risk is not evident.

162. I am concerned at the lack of assessments of Mrs A between 22 and 31 Month1, given her drowsiness and her possible UTI. As Rest Home 2's Nurse Manager, RN C was responsible for carrying out these assessments.

163. I am also concerned that there are instances where lorazepam and risperidone (prescribed for agitation) were administered when Mrs A was reported to be sleepy or wandering into other residents' rooms. As noted above, in my view, drowsiness, or wandering into other residents' rooms, does not equate to agitation.

Care planning

164. RN C's job description stated that his duties included developing nursing care plans to deliver a comprehensive and consistent pattern of care. I am concerned about the lack of care planning for Mrs A. Between 22 and 31 Month1 there are numerous records in Mrs A's progress notes of her being "very sleepy". However, no short-term care plan was put in place to monitor Mrs A in light of her increased drowsiness.

165. At the time of her admission to Rest Home 2, Mrs A was mobilising independently without mobility aids. On 4 Month2, staff noted that Mrs A was not weight bearing properly and was unsteady on her feet. Ms Bish advised that the care plan should have been updated at this time to reflect this change in Mrs A's health status. On 5 Month2, staff found Mrs A "face down on the floor". I agree with RN C that he should have amended Mrs A's care plan to show her increased falls risk following her decline in mobility.

166. RN C was accountable for directing, monitoring and evaluating nursing care provided by the care staff. I consider that Rest Home 2 staff needed more direction from RN C regarding monitoring of Mrs A owing to her increased drowsiness. Mrs A also required monitoring in relation to her increased risk of pressure areas and falls. I am critical that RN C failed to update Mrs A's care planning as her condition changed, and give appropriate instructions to Rest Home 2 staff.

Medication management and documentation

167. In accordance with his job description, RN C was also responsible for monitoring staff completion of nursing documentation to ensure that all documentation met legislative requirements and best practice guidelines, and promoting safe practice among all staff, and for ensuring that all medications were administered safely in accordance with Rest Home 2's medication policies.

168. Although RN C was responsible for ensuring that the clinical documentation was accurate, there are numerous inconsistencies and gaps in the documentation of Mrs A's medication administration. There are a number of occasions where the Signing Sheet is incomplete. In places, there is no record indicating whether the medication was given and, if not, the reason for this. For example, on 29 Month1, Mrs A's

morning and lunchtime medications were withheld, but apart from a note that she was "very sleepy + tired, unresponsive", there is no further documentation in relation to this. I consider that RN C should have identified these failures and taken steps to improve the quality of documentation.

169. Mrs A should have been administered trimethoprim each day from the time the course of antibiotics was prescribed, but the administration record does not reflect this, with a gap between the first and second doses of multiple days. There is no reason for this omission documented.

170. There are no prescriptions signed by an authorised prescriber in the medication profiles for ibuprofen, prednisone, Paracare, trimethoprim or subcutaneous fluids. Ms Bish advised that even if they were faxed directly to the Pharmacy, a signed order is required to be kept in the clinical file.

171. Rest Home 2's Medication Policy requires checks to be carried out as part of medication administration, in particular, checking of the contents of the unit dose pack or medicine label with the resident's medicine order. Mrs A's medication profile was correct, but the Signing Sheet was incorrect. A check against Mrs A's medication profile could have identified the dispensing error when the risperidone was being administered to Mrs A. I am critical that RN C did not ensure that Mrs A's medications were being administered safely in accordance with Rest Home 2's Medication Policy.

Conclusion

172. As noted above, Rest Home 2 did not have sufficient nursing hours for the number of residents. This mitigates RN C's failures to some extent. He told HDC that he expressed concerns to Ms D, but did not put any concerns in writing. However, I consider that RN C should have taken further steps to alert management to his concerns about workload.

173. RN C failed to ensure that staff at Rest Home 2 provided adequate care and treatment to Mrs A. RN C failed to maintain adequate care planning as Mrs A's condition changed and her drowsiness increased, and did not adequately assess Mrs A between 22 and 31 Month1, and failed to perform and record clinical assessments or monitor Mrs A's vital signs. RN C did not ensure that appropriate documentation was maintained by staff, or that medications were being safely administered in accordance with the medication policy. Overall, RN C failed to provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Opinion: Ms D — Adverse comment

174. As the Operational Manager, Ms D had overall responsibility for managing Rest Home 2. Her job description stated that her responsibilities included implementing a quality system compliant with the Health and Disability Sector Standards, and implementing an overall Quality Improvement Plan. The day-to-day care of Rest

Home 2 residents was overseen by Nurse Manager RN C and, as Ms D did not hold an annual practising certificate, she would ask RN C about any clinical issues. I consider it reasonable that Ms D relied on RN C to carry out his duties effectively.

175. However, I am concerned about Ms D having retrospectively altered the clinical record. On 1 Month2, care assistant Ms F added doses of ibuprofen, prednisone and Paracare to Mrs A's medication chart in error. Several months later, Ms D crossed out the additions made by Ms F and wrote "error" alongside her (Ms F's) initials, but did not record the date of the amendment.

176. Ms Bish advised that altering the clinical file at this point was not appropriate, and that Ms D should have alerted HDC to her finding, and completed an incident form, which would have allowed for "investigation and identification of corrective actions to manage risk and ensure it did not happen again as errors of this nature could be potentially life threatening to residents".

177. Although I acknowledge Ms D's explanation that she did not complete an incident form because it was four months after the event, I remind her of the importance of maintaining adequate documentation. There is no record of the date of the amendment or the circumstances leading to the error. In my view, the effective management of incidents is essential to ensure learning from errors and improvement of processes. In this case, the error indicated that there were weaknesses in Ms F's training. Completion of an incident form would have suggested an area where further training of all care staff was required.

Recommendations

178. I recommend that Rest Home 2:

a) Provide a written apology to Mrs A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

b) Report to HDC on the recent audits of its medication administration documentation, within three months of the date of this report.

c) Conduct a review of the effectiveness of the new medication policies, and report back to this Office within three months of the date of this report.

d) Review its short stay medication process and report back to HDC on any changes made, within three months of the date of this report.

e) Review its admission procedures to include an assessment of residents' competency. The procedure should include the recording of contact details for a liaising family member, any individuals holding EPOA for personal care and welfare, and clearly ascertaining whether the EPOA has been activated by medical certification, and report back within three months of the date of this report.

179. I recommend that RN C:

a) Provide a written apology to Mrs A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

b) Provide a report of his learnings from this complaint, within three months of the date of this report.

180. I recommend that the Pharmacy Council of NZ consider whether a review of Ms G's competence is warranted.

181. I recommend that Ms G:

a) Provide a written apology to Mrs A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

b) Refrain from self-checking until she has received further checking training.

c) Undertake a practice review, particularly in relation to her checking of medications dispensed, and report to HDC on this within three months of the date of this report.

182. I recommend that the Pharmacy:

a) Create a checklist for orientation processes to ensure that training for new pharmacists is consistent and comprehensive, and advise HDC of its progress within three months of the date of this report.

b) Review its SOPs in light of this report, and report to HDC on any changes made, within three months of the date of this report.

Follow-up actions

183.
- A copy of this report will be sent to the Coroner.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Nursing Council of New Zealand, and it will be advised of RN C's name.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms G's name.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the relevant district health board, and it will be advised of the Pharmacy, Rest Home 2, RN C's and Ms G's names.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent nursing advice to the Commissioner

The following expert advice was obtained from Tanya Bish:

"I, Tanya Bish, have been asked to provide expert advice on case **C13HDC01720**

Qualifications

2012 Postgraduate Master of Nursing (Hons)
2010 Postgraduate Diploma in Health Sciences (with Distinction)
2008 Postgraduate Certificate in Health Sciences
1996 Levels One and Two of the Infection Control Practitioners Certificate Course
1993 Certificate in Gerontological Nursing
1992 Bachelor of Commerce Degree
1987 New Zealand Registered Comprehensive Nurse

Professional membership

NZNO Infection Control Division, Gerontology Division
College of Nurses Aotearoa

Experience

Over 25 years gerontological nursing, management and consulting experience predominantly in residential aged care.

Two years working as a Gerontology Nurse Specialist in the community Waitemata District Health Board (WDHB).

Four years working as a Quality and Professional Development Nurse Leader for Residential Aged Care WDHB.

Advice requested

1. To provide expert advice on whether the care provided to [Mrs A] by [Rest Home 2] was appropriate with regards to:
    a. The fact that [Mrs A's] medication was not checked by a registered nurse when it arrived from the pharmacy;
    b. The delay in discovering the over-sedation and the efforts made to establish the cause of [Mrs A's] drowsiness;
    c. The management of [Mrs A's] food and fluid intake;
    d. Falls management;
    e. Pressure area prevention and assessment;
    f. Whether the instructions [RN C] provided, regarding the care of [Mrs A's] pressure areas was appropriate;
    g. Whether the policies and procedures at [Rest Home 2] were adequate;
    h. Whether the staffing levels were appropriate;
    i. Whether [Mrs A] was medically reviewed in a timely manner when she was admitted to [Rest Home 2];
    j. The appropriateness of the administration of Rivotril in light of the information [Rest Home 2] have provided to HDC regarding a standing order in place;

k. Whether [Ms D's] actions were appropriate when she was made aware that a caregiver had added medications to [Mrs A's] medication chart;
l. Whether the administration of antibiotics (Trimethoprim) was appropriate; and
m. Other comments on the care provided.

2. The appropriateness of the care provided by Operational manager [Ms D]
3. The appropriateness of the care provided by [RN C]

Information reviewed

1. Copy of [Mrs B's] complaint;
2. Copy of [Rest Home 2's] initial response to HDC dated 10 March 2014, containing a review of the incident;
3. Copy of letter from [Rest Home 2] to [Mrs B] dated 8 [Month2] 2013;
4. Copy of [Rest Home 2's] second response dated 1 July 2014;
5. Copy of [Rest Home 2's] medication policy issued 1 December 2013;
6. Copy of [Mrs A's] relevant clinical records from [Rest Home 2];
7. Copy of [Mrs A's] relevant clinical records from the public hospital.
8. Copy of Correspondence from [Mrs B] 12 February 2014
9. Copy of File note of phone call 29 July 2014
10. Copy of Coronial direction
11. Copy of Correspondence between HDC and [Ms E]
12. Copy of Letter from Nurse Manager [RN C] 17 November 2014
13. Copy of [Ms D's] response to HDC 20 February 2015

Background

On 21 [Month1], Dr K prescribed [Mrs A] 0.5mg tablets of Risperidone, to be taken three times daily and a further tablet as required. However [the Pharmacy] supplied [Rest Home 2] with 2mg tablets of Risperidone. The medication arrived at 6.00pm and was not checked by a registered nurse, as the Nurse Manager had left for the day. The medication profile showed 0.5mg to be administered three times per day. The medication administration signing sheet recorded the Risperidone as 2mg tablets three times per day.

As a result of this error, [Mrs A] was over-medicated for nine days. During this time and over the following week, [Mrs A] was sleepy, not very responsive, refused food and fluids, suffered a fall and developed a pressure sore. On 6 [Month2], she was transferred from the rest home to [the public hospital], where she died [a few weeks later].

The following standards/evidence based guidelines/contracts are relevant to this case:

- Health and Disability Sector Standards NZS 8143:2008
- Health Practitioners Competence Assurance Act 2003
- Age-related residential-care services agreement 2013
- The Code of Health and Disability Services Consumers' Rights 2009
- New Zealand Nursing Council Registered Nurse (RN) Scope of Practice and Competencies

- Medicines Care Guides for Residential Aged Care 2011
- Standing Order Guidelines 2012
- New Zealand Handbook Indicators for Safe Aged-care and Dementia-care for Consumers SNZ HB 8163:2005

1a. [Mrs A's] medication was not checked by a registered nurse when it arrived from the pharmacy

It is the responsibility of the pharmacist to ensure the right medications are dispensed according to the prescriber's orders. When the medication packs arrive at the residential aged care facility they can be checked against the prescriber's orders on the medication chart providing an additional step that improves the chance of picking up a pharmacy dispensing error.

It is current accepted good practice that medication dispensed by a community pharmacist for a resident in a residential aged care facility will be checked on arrival at the facility. Each individual medicine and the doses are listed on each blister as well as at the top of the pack.

Medicines Care Guides for Residential Aged Care (2011) recommend that this check is carried out by a staff member who has demonstrated medicines management safety competency when the medicines arrive at the rest home. There is not a requirement that this be a registered nurse however registered nurses often complete checks such as this in residential aged care facilities. It is advised that a record of items received be maintained.

In this case, [rest home] policy states that 'a senior staff member should check all packs against medication profiles and initial each pack to indicate this has been done prior to the expected start date.' The policy does not differentiate between hours when the RN is on site but states that all packs should be checked against the medication profiles.

In the incident review written by [Ms D], Operational Manager, it is stated that 'the Care Assistant (responsible for medications) on duty that evening' signed the medication in. In correspondence dated 20 February 2015 [Ms D] states that 'a full medication reconciliation was not completed'. [Ms D] had signed the medication competency tool for the Care Assistant [in] July 2013 stating she demonstrated safe medication administration.

The policy also states as part of medication administration that '3 checks' need to be carried out which include

1. Check the unit dose, eg, blister pack, or medicine label when getting the medicine from storage
2. Check the contents of the unit dose pack or medicine label with the resident's medicine order

In my view the policy covers the circumstances relating to [Mrs A] and on this occasion there was a departure in practice from the rest home policy as a check

against the medication profile should have identified a dose error. This error could have been identified at the time the packs arrived from the pharmacy or when the medication was being administered to [Mrs A] had the policy been followed. I note that subsequent policy has provided additional clarification regarding packs received after hours and medication reconciliation.

b. Delay in discovering the over-sedation and the efforts made to establish the cause of [Mrs A's] drowsiness

Health and Disability Sector Standards NZS 8134:2008 require that consumers receive services that meet their individual assessed needs, that assessment is undertaken by a suitably qualified service provider, assessment is developed in partnership with the consumer and/or family and is documented to a level of detail required to demonstrate the needs of the consumer.

[Mrs A] was new to the facility [18 Month1], having only been at the facility four days before receiving a higher dose of risperidone than prescribed.

As previously mentioned safe administration of medication should have identified this pharmacy dispensing error earlier if each person administering the medication had checked the unit dose pack against the medication profile.

As [Mrs A] was unable to effectively communicate her needs and changes in her health status to staff due to cognitive impairment she was reliant on staff identifying and responding to changes. The behaviour of residents with dementia can fluctuate from day to day and knowing the resident over an extended period of time is very helpful when identifying new concerns. It is likely staff were still developing a picture of what was normal behaviour for [Mrs A].

The care assistants documented observations they observed on a daily basis from the time of admission. Initially the progress note entries described unsettled behaviour and concerns over [Mrs A] frequently entering other residents' rooms. Some of this behaviour had been previously identified and it is not unusual for new residents with dementia to have a couple of weeks of unsettled behaviour on transfer to a new environment. [Mrs A] was seen by a Locum GP, [Dr K], on [21 Month1] who prescribed her regular medications. These were dispensed and delivered by pharmacy staff that evening.

Reports of increased sleepiness began on [22 Month1] '… very, very sleepy …' but there were also periods over the following days where [Mrs A] was mobilising and entering other people's rooms. This indicates that [Mrs A's] behaviour fluctuated during the period when the medication administered was more than that prescribed.

It is reported in the progress notes [22 Month1] that '[RN C] came to help wake her …' however no clinical assessment or vital signs are recorded in the clinical file at this time. Given this behaviour had not previously been observed it would have been prudent for the RN to document an assessment including vital signs.

On [24 Month1] a care assistant documented that [Mrs A's] urine had an offensive smell stating that she would need a 'urine spec in the morning'. The following day the Nurse Manager queried whether [Mrs A] had a urinary tract infection and faxed the GP [25 Month1] stating that [Mrs A] had offensive smelling urine and that he had been unsuccessful in collecting a sample for laboratory analysis but wondered whether she would benefit from treatment. The GP did not visit [Mrs A] but arranged an antibiotic prescription for trimethoprim. No clinical assessment or vital signs are documented in the progress notes provided.

Urine infections can be difficult to diagnose accurately in older people with cognitive impairment. Change in physical and mental status can be indicative of infection. Smelly urine can occur with infection but can also occur due to other reasons such as dehydration and as a result of eating certain foods. It would have been beneficial to have more clinical information such as vital signs and a comprehensive clinical assessment as other possibilities for change in behaviour/health status do not appear to have been explored.

[Mrs A] was prescribed five days of trimethoprim commencing on [25 Month1]. The administration chart indicates she received four doses, the first on [25 Month1] and then three consecutive doses from [28 to 30 Month1]. On [29 and 30 Month1] she was reported to be '… sleepy, tired, unresponsive … barely rousable'. It is not unreasonable to consider the sleepiness to be due to a urinary tract infection but vital signs and clinical assessment are not documented during this period.

[31 Month1] the medication error is identified. The Nurse Manger wrote in the progress notes that the medication error had occurred, that the GP and pharmacy were notified, risperidone was to be withheld until RN review the next day, that food and other medications were also to be withheld. He also reported that subcutaneous fluids were in progress and 'OBS satis'. The RN from MHSOP reported BP 150/85, P 96. At 6.30pm the Operational Manager reported on the progress of the subcutaneous fluids and reported BP 138/82. These actions are all reasonable in the circumstances.

In a rest home environment the RN is responsible for assessment, care planning and evaluation, and the direction and delegation of care staff. A short term care plan dated [18 Month1] is evident; a further short term care plan dated [26 Month1] described interventions for urinary tract infection which is appropriate. This was evaluated on [1 Month2] indicating the urinary tract infection was resolved. Further documented care planning to provide direction on the monitoring of increased drowsiness; vital signs; increased risk of pressure area skin breakdown and increased falls risk is not evident.

In summary, [Mrs A] was new to the facility and staff would have still been getting to know what behavioural patterns were normal for her. The RN was aware of the drowsiness but documentation of clinical assessment was limited. Input from the GP was sought and [Mrs A] was treated for a urinary tract infection based on information provided by the RN. Once the medication error was

identified appropriate notifications to the GP and pharmacist were made and their instructions followed.

c. The management of [Mrs A's] food and fluid intake

Fluid balance recordings and food intake records were started following the identification of the medication error. There are also multiple entries recorded in the progress notes by the care assistants describing her intake prior to admission to the public hospital. Electrolyte results do not suggest that she was dehydrated and subcutaneous infusion was used to assist to maintain hydration. Maintaining adequate food and fluid intake would have been more challenging due to cognitive impairment, sedation, and at times restlessness.

d. Falls management

At the time of admission [Mrs A] was mobilising independently without mobility aids. When her health status changed she is likely to have been at higher risk of falling during periods when she was mobilising. It was reported in the progress notes that she was not weight bearing properly and that she was unsteady on her feet on [4 Month2]. The short term care plan was not updated to reflect this change. On [5 Month2] [Mrs A] was 'found face down on the floor'. How she came to be there was not witnessed but a fall cannot be ruled out. Documenting the increased falls risk would have provided a care plan that reflected [Mrs A's] current health status but may not have prevented staff from finding [Mrs A] on the floor.

e. Pressure area prevention and assessment

As [Mrs A] became less mobile her risk of pressure related skin breakdown increased. Pressure related skin breakdown can occur quickly when there is a decrease in mobility for any reason. An initial pressure area risk assessment was completed prior to the medication error. Staff were monitoring the condition of her skin. 'Pressure marks' were reported in the notes [3 Month2]. Care assistants are generally aware of pressure care interventions. The following day the care assistant notified '[RN C]' that [Mrs A] was 'getting a pressure sore' and the notes indicate that she was given a pressure relieving cushion. On [5 Month2] a wound assessment and management plan was completed by [RN C] indicating a 'small pressure ulcer from prolonged period of inactivity/sitting. Pressure relief cushions being utilised and alternate day dressings commenced'. Pressure relieving devices assist in the management of pressure related prevention and injury.

f. Whether the instructions [RN C] provided, regarding the care of [Mrs A's] pressure areas was appropriate

The instructions [RN C] provided were appropriate. [RN C] has identified the cause and provided instruction regarding a pressure relieving cushion and wound management. Assisting in changing position is also an important aspect of prevention and treatment during periods of immobility. [Mrs A's] level of alertness and mobility fluctuated during this time. When awake she was able to independently change her position but at times she was very sleepy. General

nursing care advice regarding 'frequent changes of position' were documented on the Waterlow Pressure Area Risk Assessment. [Mrs A] was transferred to [the public hospital] on [6 Month2] with a small area of pressure related skin breakdown. [Mrs A] was transferred to hospital within a short timeframe therefore the documentation could be considered to be adequate in the circumstances.

g. Whether the policies and procedures at [Rest Home 2] were adequate

Medication Management
The Nurse Manager has documented the medications that the resident was reported to be taking at the time of admission and the carers have administered medication from this 'Short Stay Medication Record' from [18 Month1] to [21 Month1]. There is no evidence this medication chart was approved by the GP responsible for the ongoing management of this resident's care until [21 Month1]. In this instance no error occurred during this time however it is potentially unsafe practice. Whilst there are obvious challenges with getting all new admissions seen on the day of admission there should be an ability to send a medication chart to the GP for confirmation that the GP is agreeable to the resident receiving those medications until they complete their admission visit on site. Alternatively a medication chart and scripts signed by the transferring GP can be used in the interim if the receiving GP agrees.

The revised medication policy issued [soon afterwards] continues to endorse this unsafe practise:

'If a completed medication profile from their own GP is not available, short stay clients will have a "short stay medication record" completed by their prime Care Giver upon admission'

'Short stay residents will have a short stay medication record filled out by their prime care givers upon (or the RN on duty if prime care giver is not present) or before admission. This provides written authority for care staff to administer medication on behalf of the usual care giver in the absence of any orders to the contrary by the resident's GP. This form can be used on admission in the absence of a completed medication profile. Individual doses of medication are recorded on blank signing sheet as supplied by the Pharmacy …'

No policies were provided regarding the use of 'Standing Orders'. The documents provided were not consistent with the Standing Order Guidelines 2012.

Multiple instances occurred where staff practice was not consistent with policy such as failure to sign for medications administered, or if not given provide the reason.

h. Whether the staffing levels were appropriate

The New Zealand Handbook 'Indicators for Safe Aged-care and Dementia-care for Consumers' recommends two hours registered nurse input per week and 12 hours health care assistant input per consumer per week. [Rest Home 2] is reported to have 28 beds in [Month1] when the incident occurred and [RN C] was

employed for 40 hours per week. If no additional registered or enrolled nurses were employed these hours fall short of the recommendations by 16 hours per week. It is noted that he recalls advising [Ms D] that the hours provided were not sufficient to meet the requirements but these concerns were not put in writing.

i. Whether [Mrs A] was medically reviewed in a timely manner when she was admitted to [Rest Home 2]

[Mrs A] was admitted to [Rest Home 2] on [18 Month1]. She was medically reviewed within one working day as she was assessed by [Dr K] [on 21 Month1]. This would be considered to be in a timely manner.

j. The appropriateness of the administration of Rivotril in light of the information [Rest Home 2] have provided to HDC regarding a standing order in place

Two doses of Rivotril drops were administered from standing orders[31] before the medical admission review took place. A copy of the standing orders for [Dr J], the regular GP, was unable to be provided. [Dr K] was a locum GP. Three other GPs providing services had signed standing orders for Rivotril in March 2013. At the time the drops were administered the staff were acting on a list of medications they believe were able to be administered under standing orders. The Rivotril drops were discussed at the admission review with the Locum GP, [Dr K]. She wrote [21 Month1] '[RN C] wondering if could change lorazepam to Rivotril drops b/c easier to administer if required when agitated. Has prn risperidone as well if needed … I will leave meds for now … (already on regular lorazepam, might get a bit too much overlap having 2 types of benzos as well as risperidone?)'. I concur with [Dr K's] comments. Based on the standing order documents provided I recommend the Standing Orders be revoked until they have been reviewed in line with the Standing Orders Guidelines. The issuer retains overall responsibility to ensure the legislative requirements for the standing order are met. I note from subsequent correspondence that Rivotril drops have been removed from the standing orders following review of this case by [Rest Home 2] which I consider to be appropriate. Written evidence that a legal standing order for rivotril was in place in [Mrs A's] case was not able to be provided.

k. Whether [Ms D's] actions were appropriate when she was made aware that a caregiver had added medications to [Mrs A's] medication chart

Medication orders for ibuprofen, prednisone and paracare were made on the resident medication profile [1 Month2]. The ibuprofen was PRN and it appears one dose was administered on [1 Month2]. Prednisone appears to have only been administered on the [5 and 6 Month2]. A line has been drawn through these three medications indicating they have been stopped but there is no date, signature or designation. These orders on the medication chart were later reported to have been written in error by a health care assistant receiving medication from the Pharmacy.

[31] Mrs A's GP had not signed the generic standing order form which included Rivotril drops.

[Ms D] crossed out additions to the medication profile following receipt of the request for information from the Health and Disability Commissioner's Office. By this time [Mrs A] was deceased and therefore concern for resident safety could not have been the reason this action was taken. Altering the clinical file at this point was not appropriate. The appropriate action would have been to notify the Health and Disability Commissioner's Office of the finding and the circumstances. As per Standard 2.4 'All adverse, unplanned or untoward events are systematically recorded by the service …' Completing an incident form would have logged this event in the quality process allowing for investigation and identification of corrective actions to manage risk and ensure it did not happen again as errors of this nature could be potentially life threatening to residents.

l. Whether the administration of antibiotics (Trimethoprim) was appropriate

Administration of trimethoprim should have occurred each day from the time the course of antibiotics was prescribed. The administration record does not reflect this with a gap between the first and second doses of multiple days. There may have been a valid reason for not administering the medication however this reason is not clearly documented on the administration chart.

m. Other comments on the care provided

There are some omissions and irregularities that are evident in the clinical file.

1) The resident is reported to have nil known allergies on the medication charts at the facility when there is a history of medication alerts documented at the public hospital including erythromycin — rash/vomiting. The admitting facility has a duty of care to make every attempt to ensure the information they are recording is accurate. This may involve accessing previous medical notes/details. I note the information stating 'nil known allergies' was provided on the Transfer Form from [Rest Home 1].
2) There is omitted information on the medication administration signing records on multiple occasions. This includes not signing for prescribed medication with no indication why the medication hasn't been given or whether it was given but not signed for. On other occasions all medication in the morning were withheld because [Mrs A] was sleepy or she is reported to have a swollen leg but there is no evidence of monitoring of vital signs or clinical assessment.
3) The GP has written that PRN doses of lorazepam and risperidone were to be given for agitation however there are instances when these medications were administered when [Mrs A] was reported to be sleepy or wandering into other people's rooms. These behaviours are not the same as agitation. No behaviour monitoring chart was initiated to monitor behaviours causing staff concern. On [22 Month1] records indicate that [Mrs A] was given PRN lorazepam but progress notes stated she was 'very sleepy'. [23 Month1] [Mrs A] was given PRN risperidone, progress notes reported that she 'continued to enter other residents rooms'. [28 Month1] [Mrs A] was given PRN lorazepam but progress notes stated '[Mrs A] was really good'. [29 Month1]

[Mrs A] was given PRN lorazepam but there was no progress note entry for the shift.

4) Prescriptions signed by an authorised prescriber are not evident in the medication profiles provided for ibuprofen, prednisone, paracare, trimethoprim or subcutaneous fluids. These may have been faxed directly to [the Pharmacy] but a signed order is required to be kept in the clinical file.

2. The appropriateness of the care provided by Operational manager [Ms D]

The Operational manager job description outlines responsibilities relating to the 'implementation of a quality system' and 'overall quality improvement plan' as well as 'ensuring current rules, policies and procedures are available to guide all staff and visitors to ensure all regulations governing [Rest Home 2] are met'. Significant gaps in these areas have been identified.

3. The appropriateness of the care provided by [RN C]

The Nurse Manager job description outlines responsibilities relating to 'Effective nursing care', including care planning, documentation, staff supervision and meeting the legal requirements related to the Health and Disability Sector Standards, safe administration of medicines, staff training and quality improvement. Significant gaps in these areas have been identified including documentation of assessment including vital signs.

Summary of key points and opinion

[Mrs A] was new to the facility and the staff were still getting to know what her normal behavioural pattern was during the time the medication dispensing error occurred. However prior to the error there were no reports of excessive drowsiness. When [Mrs A] became excessively drowsy the RN was made aware but minimal clinical assessment was documented. Input from the GP was sought and [Mrs A] was treated for a urinary tract infection but there was little evidence that other possible reasons for her change in health status were considered. The lack of documented clinical assessment and care planning in relation to behaviours causing concern, increased drowsiness, increased falls risk including vital signs when health status changed could be considered a moderate departure from accepted practise.

Once the dispensing error was identified the GP and pharmacist were notified and appropriate care instructions were followed.

In relation to policies and procedures for safe medicines management there are numerous shortcomings described. Following safe medication administration procedures could have resulted in earlier identification of this error. Multiple findings suggest systems failure. Various unsafe practices identified in this case could be considered as severe departures from accepted practise.

Signed
Tanya Bish NZRCompN, MN (Hons)"

Appendix B — Independent pharmacy advice to the Commissioner

The following expert advice was obtained from Julie Kilkelly:

"I have been asked to provide further advice to the Commissioner on -
Case number: C13HDC01720
Parties: [Mrs A] (dec) and [the Pharmacy]
with reference to :
i) The standard of care provided and whether this is accepted practice.
ii) Any departures from i) above and how significant these are.
iii) How the provided standard would be viewed by my peers.

I have been a NZ registered practising pharmacist since 1990 and have worked in both community and hospital settings. I currently practise in a community pharmacy that I have been a co-owner of since 2002. I was recently a member of the NZ Pharmacy Council's Reference Group for the review of the scope of practice and associated competence standards for pharmacists.

I served two terms as a member of the West Coast District Health Board (2001–2007) during which time I chaired the Community and Public Health Advisory Committee and was a trustee of the West Coast Primary Health Organisation from 2002–2006 and I am the currently their independent Chairperson.

After review of the documents provided (as listed below) I have been asked to provide an opinion on the care provided by:

1) **[Ms G]**, specifically
   a) The accepted process for dispensing this kind of medication.
   b) The appropriateness of the process followed by [Ms G] in the dispensing of [Mrs A's] medication.
   c) The appropriateness of the steps she has taken since the error.
2) **[The Pharmacy]**, specifically
   a) The appropriateness of the policies and procedures in place at the Pharmacy at the time.
   b) The appropriateness of changes made to the policies and procedures since the error.
   c) The adequacy of [Ms G's] orientation and training.
   d) The appropriateness of steps taken in light of errors/concerns regarding [Ms G] (prior to the error).
   e) The appropriateness of steps taken in light of errors/concerns regarding [Ms G] (after the error).

Documents/information provided:

1) [Mrs A's] complaint and subsequent correspondence

[The Pharmacy]
2) [The Pharmacy's] response (dated 10 February 2014)

3) Response to notification (21 October 2014)
4) Employment file for [Ms G]

[Ms G]
5) Response to notification: [Ms G] (dated 20 October 2014)
6) Letter from [Ms G] (dated 22 December 2014)

The Pharmacy Council of New Zealand advised HDC that [Ms G]:
— gained a BPharm [overseas];
— registered in New Zealand in the mid 90s;
— was accredited to dispense the Emergency Contraceptive Pill in 2002; and
— is participating in the Council's recertification requirements.

I will address your questions under each heading that you have used in your request for advice but first will give some background information to allow the advice to be put into the correct context and legal framework.

The **Code of Ethics** was prescribed by the Pharmacy Council of New Zealand pursuant to Section 118(i) of the Health Practitioners Competence Assurance Act 2003 and came into effect from 01 January 2011. The principles of the Code of Ethics are intended to capture the philosophical foundation of pharmacy practice and to express the responsibilities and professional values that are fundamental and inherent to the Pharmacy profession. These principles apply to all pharmacists, irrespective of whether they treat, care for or interact directly with patients and the public. The Code serves as a basis for pharmacists to monitor their own ethical conduct and that of their colleagues. A pharmacist is professionally accountable for their practice, which means being responsible for what they do or do not do, no matter what advice or direction a manager or another professional gives them. A pharmacist may be faced with conflicting professional or legal responsibilities; therefore they must use their professional judgement when deciding on a course of action.

The Code of Ethics is to be read in conjunction with current Acts, Regulations and Codes of Practice and standards that directly or indirectly impact on the professional practice of pharmacy. In particular, **Health and Disability Service — Pharmacy Services Standard NZS 8134.7:2010** which creates a solid foundation to ensure pharmacy services reflect good practice and has been part of Ministry of Health Pharmacy Audits since 1 July 2010.

The **Pharmacy Council of New Zealand** was established under the Health Practitioners Competence Assurance Act 2003 (HPCAA). The Council's primary role is to protect the health, safety and wellbeing of the public by ensuring pharmacists are competent and fit to practice. The Council is therefore responsible for setting standards for pharmacist education and competence.

All pharmacists practising in New Zealand in the Pharmacist Scope of Practice must have a current annual practising certificate, which [Ms G] does and as part of this they must be enrolled in an approved recertification programme (Enhance 2.0)

to maintain their competence, and also to develop and adapt their practice to the ever changing health environment.

The **Pharmacy Council Medicines Management Competence Framework** outlines four levels of medicines management services. These recognise the relationship between the required competency (knowledge, skills, attributes) and the complexity of the medicine management issues. They provide a blueprint for describing the competencies and behaviours of pharmacists in their daily practice. Given [Ms G's] work history and educational record (as evidenced by her included curriculum vitae) I would view her practice as Level A (entry level for all pharmacists) but an experienced pharmacist at this level. At this level [Mr L], being an experienced owner pharmacist of [the Pharmacy] would be expected to demonstrate competencies beyond [Ms G's] especially in relation to management tasks (staff and practices). [Mr L] may well have additional competencies at Levels B and higher but this is not applicable to the incident being reviewed.

The **Pharmacy Council Competency Standards** set out the expected requirements for pharmacists in order to ensure the safe and quality use of medicines to optimise health outcomes. I will refer to the set of standards in place at the time of the incident which were revised and updated in 2010, not the recently updated version.

1) Care provided by Pharmacist [Ms G]

a) Accepted process for dispensing this kind of medication and
b) appropriateness of the process followed.

The Code of Ethics states that you (as a practising pharmacist) must practise in accordance with accepted best practice guidance and the current version of the Health and Disability Services — Pharmacy Services Standard or equivalent (Principle 5.4), ensure that appropriate standard operating procedures are in place, maintained and followed. (Principle 7.8) and that your actions do not prevent others from complying with their ethical, legal and professional obligations, or present a risk to patient care or public safety (Principle 7.7).

The relevant Pharmacy Council Competence Standards are **6.2.2** — Follows workplace dispensing criteria when dispensing a prescription item, **2.3.2** — For each medicine checks that the dosages and methods of administration are optimal, **4.1.3** — Supports the work of colleagues in the workplace by working in partnership to ensure safe practice and **1.1.2** — Maintains a consistent standard of work within relevant scope of practice.

These standards were not fully adhered to as there were authorised (as per Ministry of Health Audit 2 November 2010) Standard Operating Procedures (SOPs) in place at [the Pharmacy] for Prescription Assessment and Clinical Check (Document C35), Label Generation and Dispensing Medicines (Document C36), Accuracy Checking (Document C37), and Dispensing Medico Packs (Document D01) at the time of the incident which [Ms G] should have been following.

Prescription Assessment and Clinical Check SOP (Document C35) — This document states that before any label preparation and dispensing occurs that a pharmacist should complete a clinical check on the prescription. This includes assessment of appropriate dose for age, weight, renal function and likely indication as well as compatibility with other medicines (drug interactions).

[Ms G] notes in her response to notification (dated 20 October 2014) that she would usually check these things. For some reason she did not heed the computer software warning interaction (sedation) or note the relatively high dose that she had entered (for its likely indication in) this case, selected, packed and checked. A consistent standard has not been demonstrated by [Ms G] in this instance.

Accuracy Checking SOP (Document C37) — This SOP specifies that the labels and dispensed medicines must be checked against the original prescription and that self-checking is not recommended and that whenever possible this check should be done by second person. It does state that if self-checking cannot be avoided that the 'mental' and 'physical' activities should be separated by another task, for example, by dispensing another prescription. When errors are picked up at this point they should be recorded in a 'near miss' log and reviewed.

There are occasional times when self-checking cannot be avoided, however, the staffing levels in the dispensary at [the Pharmacy] at the time of this error (5 staff) would have been adequate to allow a second person to check [Ms G's] data entry and dispensing and thus hopefully would have prevented the error.

Not only was [Ms G's] decision to self-check a deviation from the SOP but I believe that it was a significant error of judgement on [Ms G's] part not to have another person check her work, especially given her past history of errors (as evidenced by the enclosed incident details and records of meetings detailing previous errors).

Dispensing Medico Packs SOP (Document D01) — This procedure clearly states:

i) … that the medication is keyed into the computer and for unit dose packaging a 'Patient Medication Profile' is printed for the patients file and this is cross checked against the authorised record (in this case the prescription as no rest home practitioner signed medication chart/profile was available at this stage, which is not uncommon when the patients are new residents or a change is made).

   In [Ms G's] response to notification, dated 20 October 2014 there is no mention of this check occurring, although she does say that the medication chart was printed at 14.58pm.

ii) … Assemble all the medications required for the pack and get a pharmacist or second dispensary staff member (there were 5 staff working in the dispensary on the day this error occurred, according to [Ms G's] response) to sign off correct medications against authorised record.

> [Ms G] did not do this and chose to select the stock herself. This is a direct breach of the SOP and in fact an amendment had been made to the SOP, at [Ms G's] request (June 2013) that she preferred not to sign off on this step.

[Ms G] notes in her response to notification (dated 20 October 2014) that she would have picked the medicines from the shelves using the prescription not the labels. If this is the case then [Ms G] should have been able to pick up her earlier data entry error where she had keyed in the incorrect strength. There is some discrepancy here as [Mr L] in [the Pharmacy's] response (dated 10 February 2014) and in his report to [the] DHB Portfolio Manager (dated [2013]) and also in his letter to Ms Theo Baker, Deputy Commissioner (dated 21 October 2014) states that the medicines were picked against the computer generated drug chart and not checked back against the prescription. Nevertheless, regardless of whether the prescription or the incorrectly generated drug chart was used due care and attention was not taken by [Ms G] which resulted in the incorrectly entered medicine being picked, packed, checked and administered to [Mrs A] for several days.

[Ms G's] failure to do an appropriate clinical check (as per SOP C35), choice to self-select medicine (despite SOPD01 stating to get a second person to check selection) and failing to complete a through final accuracy check (as per SOP C37) is a significant departure from the required standard of care and accepted practice expected of an experienced dispensing pharmacist. Given the authorised procedures in place at the Pharmacy at the time of the error, in my opinion following review of all the documentation provided this would appear to me a person related error, rather than a systems error.

Everyone makes mistakes at times, as we are all human and the fact that [Ms G] keyed the incorrect strength of medicine into the computer is an acceptable error but not noticing or ignoring warnings about sedation (due to interacting drugs which should make you think again and have a closer look at combinations and dosages) and then choosing to do all steps in the dispensing process herself not only put the patient at risk but also prevented others from complying with their ethical, legal and professional obligations.

In my opinion these actions taken by [Ms G] are a direct breach of her professional and legal responsibilities and thus would not be viewed favourably by her peers.

c) The appropriateness of steps taken since the error.

There are 2 elements to this. Firstly, [Ms G's] actions immediately after being notified of the error and secondly steps she has taken since the error to minimise the risk of a similar event occurring.

The related Pharmacy Council Competence Standard is **1.1.5** — Works accurately to minimise mistakes, acts immediately to rectify harm arising from mistakes and documents errors and the steps taken to prevent these.

Dispensing Errors SOP (Document K06) — the purpose of this document is to ensure that the correct procedures are followed in the event of a dispensing error. It appears robust and from review of the documentation provided it would seem that all procedures have been followed, although it would seem that there was somewhat of a lag between fixing the error following notification ([31 Month 1]) and the subsequent paperwork trail (Incident Report Form dated [8 Month2], PDA Incident Notification dated [11 Month2] and apology letter to family dated [12 Month2]). Sometimes these events do take time to pan out but the incident should be recorded immediately following notification and correction of the error.

It would appear (from [Ms G's] response to notification dated 20 October 2014) that [Ms G] assumed that [another staff member] had logged the incident and notified [Mr L] (the director/pharmacist) of it. It is never safe to assume and [Ms G] should have clarified this with [the other staff member] as soon as possible. The SOP does not specifically state that [Mr L] be informed immediately of any dispensing errors, however this point was discussed at a staff meeting [earlier in 2013] and the staff's obligation to inform [Mr L] immediately following the initial phase (confirming and fixing the mistake) was made very clear.

[Mrs B's] summary of dealings with [Rest Home 1], [Rest Home 2] and various other people makes no mention of any phone calls from either [Ms G] or [the Pharmacy] director ([Mr L]); however, this summary only records events up until [2 Month2]. [Ms G] does mention in her response (dated 20 October 2014) that she apologised to [RN C] and [Ms D] at [Rest Home 2] and checked on [Mrs A's] condition on [1 Month2]. [Mr L] spoke to [Mrs B] on [11 Month2] and apologised for the error.

[Ms G] did write an appropriate formal apology letter to [Mrs B] dated [12 Month2] in which she apologises for the error, notes that [the Pharmacy's] procedures are robust and that this situation arose from human error. [Ms G] also includes measures that have been put in place to prevent a similar error occurring again and states that if [Mrs B] is not satisfied with the Pharmacy complaints resolution process then she has the right to contact the Office of the Health and Disability Commissioner and provides the number.

Since the error, according to [Ms G's] response notification dated 20 October 2014 she has added tablet descriptors to pack labels, which she finds helpful. These are another safety check as they describe the appearance of the tablets that have been entered on the computer to go into the pack. They do not, however, prevent all errors as incorrect data entry can be carried over to these too.

[Ms G] requested that the Pharmacy date stamp be altered to include initialling boxes for the inputter, the dispenser and the checker, which is very appropriate and used by a lot of pharmacies.

Another check process was added in to the Medico Pack Dispensing SOP so that data entry is checked by an additional dispensary staff member. [Ms G] requested an additional new stamp to identify the people involved in each of these steps. I consider this to be unnecessary and it is likely to be a significant hold up in the dispensing process and would likely interrupt dispensary flow and efficiency. If the original SOP had been followed the error would not have occurred.

[Ms G] states in her response letter that immediately following the error she had all her work checked and that self-checking is rarely done now. I am of the opinion that [Ms G] should never self-check unless she has undergone some remedial training as there are a significant number of incident reports (before and after this error) included in the correspondence involving her work. [Ms G] has requested according to her response to go on a checking course. I am unaware if such a course exists, however [Ms G] could do a Practice Review and identify checking as one of her deficiencies and obtain advice from the Enhance Co-ordinator as to the next steps to take to remedy this.

2) Care provided by [the Pharmacy]

a) The appropriateness of the policies and procedures in place at [the Pharmacy] at the time.

There were authorised (as per Ministry of Health Audit 2 November 2010) Standard Operating Procedures (SOPs) in place at [the Pharmacy] for Prescription Assessment and Clinical Check (Document C35), Label Generation and Dispensing Medicines (Document C36), Accuracy Checking (Document C37), Dispensing Medico Packs (Document D01) and Dispensing Errors (K06) at the time of the incident which all staff should have been following.

In my opinion all these documents are appropriate, straight forward and practical and constitute good practice procedures. It would appear that they are reviewed regularly in consultation with staff (as per some of the staff meeting notes), are freely available for staff to consult and form part of the orientation process for new staff.

Documentation of events (incidents, near misses, staff discussions — both collective and individual) is extensive which signals good management practice.

b) The appropriateness of changes made to the policies and procedures since the error.

The Dispensing Medico Packs SOP (D01) has been amended to include the following:

- a **clinical accuracy check** — a good addition to remind staff to do this every time.
- Foil, header card and dose pack chart are printed and **cross checked** against the new prescription or latest medication chart (rest home)

which has the doctors signature on it — a good reminder to check against the authorised record only

- a **new step** has been added where a pharmacist checks the accuracy of the data entry and initials this in 2 places (the checked box on the date stamp and in a certain column of a newly developed log sheet) — this seems an unnecessary step to me which is likely to reduce efficiencies while adding little value as the final accuracy checker could check data entry, stock selection and counts against the authorised record.
- The **statement, Self-checking is not recommended** has been added — this does not prohibit it but signals that it is not good practice.
- **sealing of the pack prior to the final accuracy check** (tablet count) — I do not consider this to be a safe procedure if the pack contains many tablets similar in appearance or alternating dose regimens as, in my opinion, it is too hard to distinguish some tablets from others and accurately count tablets when they are jammed in blisters.
- a **note** is attached to the pack if fridge items or other non-packed items are to be given out with the pack — an appropriate addition to prevent these items being missed.

In his letter to [the HDC] Complaints Assessor (dated 10 February 2014) [Mr L] states that the pharmacist responsible for the error ([Ms G]) has been spoken to about the error by management and has been involved in the investigation and review of procedures, which constitutes good management practice and signifies collective responsibility. He also states that all pharmacists in the Pharmacy have been made aware of the error and the importance of following the SOP's has been highlighted. This is also good practice and a reminder that staff need to work collectively to reduce errors.

c) The adequacy of [Ms G's] orientation and training.

When joining the staff of [the Pharmacy] [Ms G] had had 9 years previous experience (4 full-time) as a retail pharmacist at [another pharmacy] (as stated in her Curriculum Vitae). She initially started work as a regular pharmacist and spent 6 months doing this job before she moved to the rest home and blister packaging area of [the Pharmacy]. [Ms G] had worked in this type of role in her previous job so it was not completely new to her.

In his letter to Ms Theo Baker, Deputy Commissioner (dated 21 October 2014) [Mr L] gives a synopsis of the orientation/training for dispensary staff, particularly in relation to the knowledge and understanding of the Standards of Practice (SOP's). [Mr L] stated that he spent one-on-one time with [Ms G] going through relevant SOP's and explaining how the tasks were carried out and that any new tasks were demonstrated by him, expectations clarified and feed-back sought. This would seem sufficient to satisfy orientation requirements but it is somewhat at odds with [Ms G's] account of her orientation and training in her response to notification (dated 20 October 2014) in which she implies that her orientation and training was deficient and she could not recall how to use computerised systems for accessing SOP's although she did know where the hard copies were kept. It is not unusual for

pharmacies to keep hard copies of SOP's in folders or file boxes for ready access and have computerised systems for updating SOP's as they fall due. Some pharmacies have checklists or SOP's for orientation processes so that nothing is missed and training is consistent for all staff. Nothing like this was included with the correspondence but [the Pharmacy] may have one.

d) Appropriateness of steps taken in light of errors/concerns regarding [Ms G] (prior to the error).

It would appear from the correspondence that several incidents relating to errors were recorded by [Mr L] (the director/pharmacist) and discussed with [Ms G].

In his letter to Ms Theo Baker, Deputy Commissioner (dated 21 October 2014) [Mr L] states that failure to comply with SOP's had been discussed with [Ms G] and she was given a copy of the relevant SOPs for dispensing medico packs prior to this incident at a staff meeting where errors were specifically discussed. In the amendment made to the original Medico Pack Dispensing SOP (D01) at this time it specified that [Ms G] would prefer not to sign off correct stock selection against the authorised record. This was because she did not feel comfortable signing this off due to some previous errors she had made at this step. After discussion with [Mr L] it was decided that [Ms G] would neither select the stock for packing or sign it off which meant that 3 or 4 people were now involved in a normal cycle of blister packs.

From the enclosed correspondence it is apparent that [Mr L] did take the errors seriously and did try to work with staff, and in particular [Ms G] to prevent recurrences occurring. Procedures were altered to prevent system based errors and monitor error rates.

It would appear from the records provided that [Ms G] had a habit of not notifying [Mr L] (director/pharmacist) of detected errors despite him reminding her to do this (including in writing) and reiterating it at various times.

In the copy of [Ms G's] individual employment agreement in the Your Position and Duties Section (5.3) it is stated that in carrying out any of your duties you shall at all times carry out, and comply with all reasonable policies, rules, instructions and directions of the Company. This would include SOP's. Failure to do this (particularly repeatedly) could have been viewed as a breach of her contract, serious misconduct or unsatisfactory work performance and therefore could potentially have constituted part of a more formal disciplinary process.

[Ms G's] job description also included 2 key tasks, ensuring prescriptions are safe and appropriate for the patient and ensuring all prescriptions are correct before they are given out to the patient and the performance indicator for this was 100% compliance with legislation, contracts, professional obligations,

ethical obligations and pharmacy standard operating procedures hence a performance review would have been appropriate.

Performance reviews and disciplinary processes are a significant intervention but may have focussed the seriousness of the issue and early intervention may have prevented the error under investigation. I am unsure whether either of these measures were taken but I believe they would have been appropriate given the serious nature of the issue (patient safety) and seemingly repeated breaches.

e) Appropriateness of steps taken in light of errors/concerns regarding [Ms G] (after the error).

The Dispensing Medico Packs SOP (D01) was amended to include extra safety checks as detailed in section b) above. Most of these amendments were appropriate, however you can only operationalise tasks to a certain degree before efficiencies are lost. Because the dispensing process involves people there will always be an element of risk that processes can minimise but not fully eliminate.

[Ms G] was obviously upset and distressed by the incident and [Mr L] did take proper steps to refer her to appropriate agencies (Pharmacy Defence Association) and an offer of counselling was made.

[Mr L] has spoken extensively to [Ms G] about the error and she has been involved in the subsequent investigation and procedure review which is appropriate. Other pharmacy staff have also been made aware of the error and the need to follow SOP's all of the time has been discussed with all staff which is also appropriate.

I am unaware if any formal disciplinary process has been commenced, though this in my opinion would have been appropriate given the seriousness of the error in light of patient safety and the risk to [the Pharmacy's] reputation from repeated errors.

Julie Kilkelly MPS MNZCP"