

SHERIFFDOM OF GRAMPIAN, HIGHLANDS & ISLANDS AT INVERNESS

[2016] FAI 7

B326/15

DETERMINATION

BY

SHERIFF MARGARET M NEILSON

UNDER THE FATAL ACCIDENTS AND SUDDEN DEATHS INQUIRIES (SCOTLAND)
ACT 1976

into the death of

MARGARET ANN FORREST

INVERNESS, 23 May 2016

The sheriff, having resumed consideration of the Fatal Accident Inquiry into the death of Margaret Ann Forrest, determines in terms of section 6 of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 as follows:-

In terms of section 6(1)(a)

The late Margaret Ann Forrest (date of birth 27 March 1927) of The Flat, 6-8 High Street, Kingussie, died in Raigmore Hospital, Inverness, on 14 November 2013.

In terms of section 6(1)(b)

The cause of Mrs Forrest's death was:-

- i(a) bronchopneumonia; (b) probable gliclazide induced hypoglycaemic brain injury;
- ii cardiac amyloidosis as a result of the consumption of the medication received by her in error.

In terms of section 6(1)(c)

Had the staff member who handed the Medisure pack to the deceased followed process steps 1 to 4 specified in Boots Standing Operating Procedure 006, Version 5, then the death would have been prevented.

In terms of Section 6(1)(d)

There were no defects in any system of working which contributed to the death of Mrs Forrest. Had the system of working been followed the accident would not have occurred.

In terms of section 6(1)(e)

There are no other facts which are relevant to the circumstances of the death of Mrs Forrest.

Findings in fact

(1) Margaret Ann Forrest, aged 86, lived alone at The Flat, 6-8 High Street, Kingussie.

(2) She was in generally good health with the exception of some age related conditions for which she was prescribed a number of different medications. She enjoyed travelling and had continued to do this into her 70s and 80s. She lived independently in the flat above the shop which belonged to a family trust and which was, at that time, run by her son William Forrest. He provided her with some help, for example, by carrying her shopping upstairs. She was able to travel independently on the bus, clean her own flat and generally look after herself. She did not have any carers.

(3) She had become confused about her medication and on around 1 October 2013 her GP decided that it would be helpful for her to receive her medication in a “dosette box” device.

(4) These devices were described variously by different witnesses as a dosette box, an MDS (Monitored Dosage System), a Medisure (a brand name) pack or box, a DDS (Domiciliary Dosage System) and finally the generic “compliance aid”. It was clear from the evidence that the witnesses using these different designations were talking about the same thing.

(5) Medisure packs are a packaging system for medicines, primarily for tablets and similar, where the medicines are removed from the manufacturers’ original packaging and repackaged within the compliance aid unit. They contain sections of blister style packaging laid out and labelled with the days of the week and further sections for times of day (either 2 sections for night and morning or 4 sections for morning, noon, evening and night). Medisure packs are made up in four week cycles in four 1 week packs.

(6) The deceased's family were completely unaware of her confusion in relation to her medication.

(7) The plan was for her four-weekly prescriptions to be dispensed by the pharmacist into 4 Medisure packs, one of which she would pick up every week at the pharmacy. She required 9 different medicines to be dispensed into the packs.

(8) She attended the pharmacy and uplifted Medisure packs on Thursday 24 October 2013 and Thursday 31 October 2013. On these occasions she was asked to sign the DDS book (Crown production 13) when uplifting her pack.

(9) On or around Thursday 7 November 2013 she again attended at the pharmacy to return an old Medisure pack and uplift a new one. On this occasion she was not required to sign the DDS book.

(10) On this occasion the deceased was wrongly handed a Medisure pack meant for another customer of the pharmacy, Mrs Florence Frost.

(11) Mrs Frost's medication included a diabetic medication, gliclazide, which can be extremely dangerous for people for whom it is not prescribed and who are not diabetic.

(12) Gliclazide (which is one of a group of medicines called sulfonylureas) is prescribed widely for type 2 diabetes (not insulin dependent diabetes). It lowers the blood sugar. It can cause hypoglycaemia. If someone who is not diabetic takes it, it can be very detrimental. It will lower the blood sugar when that is not the desired option. It is very widely prescribed in hospital and in the community.

(13) On Tuesday 12 November 2013, the deceased's son, William Forrest, went to the deceased's flat as he had not heard from her for a couple of days.

(14) On entering the flat he found her collapsed and unconscious in the hallway.

(15) Paramedics were called and attended and the deceased was taken to Raigmore Hospital in Inverness.

(16) William Forrest handed the paramedics the Medisure pack that he had found in the bedroom of his mother's flat.

(17) At the hospital, Eleanor Cattnach (Mr William Forrest's partner who is a trained nurse and who worked there at the time) was allowed into the "resus" area to speak with the doctor. She noticed that the Medisure pack was meant for a Mrs Florence Frost and saw that there was gliclazide in it. She explained to the treating medics that the patient was not in fact Mrs Frost but Mrs Forrest, she having been alerted by her partner that his mother was being brought in. She told the treating doctors that her mother-in-law was not diabetic. At that stage it was realised that Mrs Forrest had been given the wrong medication.

(18) Mrs Forrest did not regain consciousness and died on 14 November 2013 at Raigmore Hospital in Inverness as a result of taking the gliclazide medication meant for another patient.

(19) Boots UK Limited ("Boots") ran the pharmacy in the High Street in Kingussie from where the deceased uplifted the incorrect pack.

(20) The responsible pharmacist for that pharmacy was Ms Nichola Ferguson. Other dispensers, dispensing assistants and healthcare assistants worked in the pharmacy as well.

(21) It is impossible to determine who handed the incorrect Medisure pack to Mrs Forrest. It must have been one of the employees of Boots UK Limited who was working in the pharmacy on the day in question.

(22) Boots UK Limited have standard operating procedures for a number of processes. In particular they have Standard Operating Procedure 006, Version 5 which relates to the dispensing of medication.

(23) Had process steps 1 – 4 of Boots UK Limited Standard Operating Procedure 006, Version 5 been observed and followed, Mrs Forrest would not have been handed the medication meant for another customer of the pharmacy.

(24) Boots UK Limited were the defenders in a personal injury action raised in the Court of Session by various members of the deceased's family. For the purposes of that action, liability was admitted. Boots UK Limited admitted being vicariously liable for the negligence of one of their members of staff in handing the wrong Medisure pack to Mrs Forrest.

(25) Boots UK Limited have apologised publicly for the error.

(26) The medication dispensed into the two Medisure packs meant for Mrs Forrest and Mrs Frost was correctly dispensed, labelled, checked and bagged. The error was not at the dispensing stage but at the handover stage. The quad stamps on the deceased's prescriptions had not been completed.

(27) The pharmacy in question, being situated in a small community, had a number of regular customers, including the deceased, who were well known to the pharmacy staff.

(28) After the accident all members of staff at the pharmacy including the pharmacist underwent refresher training on the company's relevant Standard Operating Procedures.

(29) Following the death of Mrs Forrest Boots UK Limited used the circumstances in an anonymised case study version, in their publication "The Professional Standard" sent to over 5,000 pharmacists in their employment in 2014.

Note

Introduction

[1] This inquiry was held in terms of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 with the objective to identify in terms of section 6(1)(c) of said Act whether there were any reasonable precautions whereby the said error and subsequent death might have been avoided, to identify in terms of section 6(1)(d) of said Act, whether any defect in the system of working in the said pharmacy contributed to the said error and subsequent death and, in particular, to examine the pharmacy Standard Operating Procedures for the handing out of dispensed medicines to the patient or representative, and to publicly examine in the public interest all of the circumstances surrounding the dispensing of medication to the vulnerable elderly. The inquiry took place over four days.

[2] Section 6(1) of the Act requires the sheriff to make a determination setting out the following circumstances of the death so far as they have been established to his or her satisfaction:-

- a. Where and when the death and any accident causing the death took place;
- b. The cause or causes of death and any accident resulting in the death;
- c. The reasonable precautions, if any, whereby the death and any accident resulting in the death might have been avoided;
- d. The defect, if any, in any system of working which contributed to the death or any accident resulting in the death; and
- e. Any other facts which are relevant to the circumstances of the death.

[3] The only method of establishing those circumstances is by the assessment of the evidence led by the procurator fiscal and any other interested party represented at and participating in the inquiry. It has often been said that a fatal accident inquiry is concerned with fact finding and not fault finding. The purpose of the inquiry is not to attach fault to any person but to inquire into all the circumstances of the accident and the death in order to discover the truth, identify any reasonable precautions which might have been taken and ascertain if any lessons can be learnt which might serve to prevent the reoccurrence of any similar accident.

[4] At this inquiry parties were represented as follows:-

For the Crown – Mr Alasdair MacDonald, Procurator Fiscal Depute,

For the Forrest family – Mr Steven Forrest,

For Nichola Ferguson, Registered Pharmacist - Ms C Mitchell, Counsel,

instructed by Murray Ireland, Solicitors; and

For Boots UK Limited - Mr B Smith, Advocate, instructed by Burness Paul,
Solicitors.

I am grateful to all representatives for their careful conduct of the inquiry and their considered submissions.

[5] The Crown lodged a comprehensive inventory of productions as follows:-

1. Intimations.
2. Autopsy report.
3. Medical records (GP).
4. Medisure record (Forrest).
5. Medisure record (Frost).
6. Medication record (Forrest).
7. Medication record (Frost).
8. Hospital records (Raigmore).
9. Medisure pack (Frost).
10. Serious dispensing incident report form.
11. Boots SOP (Standard Operating Procedures) 006, Version 5.
12. SBAR prepared by NHS Highland Lead Pharmacist dated 25 November 2013.
13. DDS book.
14. Album of photographs.

[6] The Forrest family lodged an inventory of productions (not all of which were referred to during the course of the inquiry and some of which were objected to and deemed irrelevant to the inquiry) as follows:-

1. Standards for Registered Pharmacies, September 2012, General Pharmaceutical Council.
2. Responding to complaints and concerns September 2012, Guidance Note, General Pharmaceutical Council.
3. Letter from General Pharmaceutical Council to COPFS received 10 July 2014.
4. Three extracts from Boots website.
5. A newspaper report on the death of a patient from taking the wrong medication.
6. Newspaper report on the death of a patient who was given the wrong prescription.
7. One page extract from a report of the Office for National Statistics on An Aging of the UK Population.
8. One page extract from a Parliamentary report on An Aging Population.
9. One page extract from a report from Nesta.
10. Defences lodged in Court of Session action by Boots UK Limited.

[7] For Boots, there was lodged a report from Dr José Moss, Deputy Superintendent Pharmacist, Boots UK Limited, dated February 2016, with attached appendices.

[8] At the start of the inquiry, before any oral evidence was led, the Crown lodged a joint minute which was read into the record. In addition, a further production was lodged by the Crown. This was the police statement given by Nichola Ferguson. Although represented at the inquiry, Nichola Ferguson was no longer a compellable

witness and had elected, as she was perfectly entitled to do, not to give evidence in person. The lodging of the statement was not objected to by any party and was labelled crown production 15.

[9] The following witnesses gave oral evidence to the inquiry:-

1. Detective Constable Craig Still, Police Service of Scotland.
2. William George Forrest (son of deceased).
3. Eleanor Cattnach (partner of William George Forrest).
4. Detective Inspector Alan Ross, Police Service of Scotland.
5. Nikki Marie Winter (employee of Boots, Kingussie).
6. Joan Harrison (employee of Boots, Kingussie).
7. Eva Christina Oden (employee of Boots, Kingussie).
8. Thomas Ross, Head Pharmacist, South and Mid Highlands, NHS Highland.

[10] Other witnesses on the Crown list of witnesses did not require to be called because of the existence of the joint minute which had been entered into and read into the record, which included the evidence of those witnesses.

[11] For Boots UK Limited, evidence was led from Dr José Moss, Deputy Superintendent Pharmacist at Boots UK Limited.

[12] Different witnesses (and representatives) referred to the compliance aids provided to the deceased and other patients by different names [see finding in fact number 4]. For the sake of consistency I have generally chosen to use the term “Medisure pack” as it was the term most commonly used throughout the inquiry. I

recognise however that that may not have been the term used by particular witnesses in their evidence.

Witnesses

[13] I found the witnesses who gave oral evidence to be generally credible and reliable. I gained the impression that they were trying to assist the court as best they could. The witnesses who worked within Boots pharmacy at Kingussie were largely consistent in their evidence. None of them were able to say conclusively who had handed the medication pack to the deceased. All gave evidence to the effect that they understood the Standard Operating Procedures and that the way that Medisure packs are handed to patients has now been tightened up to ensure compliance with the Standard Operating Procedures.

[14] The responsible pharmacist in charge of Boots, Kingussie branch, at the relevant time was Ms Nichola Ferguson. Her statement to the police was introduced (Crown production 15) as hearsay evidence. She is now based in Northern Ireland and was not a compellable witness. She chose to exercise her right not to give oral evidence, as she was entitled to do. While her evidence is contained in the police statement spoken to by Detective Constable Craig Still, it has obviously not been subject to testing by cross-examination.

[15] The Crown, at the preliminary hearing, had provided an undertaking not to seek to prosecute Nichola Ferguson. At the same time an undertaking was given by Mr Steven Forrest on behalf of the Forrest family not to seek any private prosecution against

Nichola Ferguson. This was done, partly at least, in the hope that she might attend voluntarily to give evidence, albeit she could not be compelled to do so. This she chose not to do.

[16] The Crown also indicated during the course of the inquiry, before any evidence was led from employees of Boots, Kingussie, that they were not seeking to bring any prosecution against any individual employees of Boots. An undertaking was given by Mr Steven Forrest on behalf of the family not to seek to bring any private prosecution against any individual employee of Boots, Kingussie. The purpose of this was so that the witnesses could be advised that they could, and should, answer freely any questions put to them without the fear of incriminating themselves. I am satisfied that the witnesses employed by Boots who gave oral evidence did so freely.

Section 6(1)(a) and (b)

[17] The date, time, place and cause of death were all a matter of agreement and contained in the joint minute lodged in this case.

Section 6(1)(c)

[18] It was very clear from the evidence that there was no issue with the medication dispensed into the Medisure pack for Margaret Forrest nor indeed into the Medisure pack for Florence Frost. Both Medisure packs were correctly dispensed in accordance with the GP's prescription. The error was that the wrong pack was given to the wrong patient, (the 'handover stage').

[19] It was clear from the GP notes that the deceased had become quite confused about her medication, although her family were unaware of this (Crown production 3 – GP records – entry at 1 October 2013).

[20] Medisure packs are made up in four week cycles in four 1 week packs. Generally they are made up for four weeks in advance and then stored on shelves for uplift as and when required, generally weekly.

[21] It was clear from the evidence and photographs (Crown production 14) spoken to by DC Craig Still, that the Medisure packs for customers of the pharmacy with surnames beginning with 'F' had been stored together on the same shelf. It was apparent that they were not in strict alphabetical order but this played no part in the accident taking place. Even had they been in strict alphabetical order it would still have been possible for the member of staff to pick up a pack belonging to someone other than the person it was meant for.

[22] Some of the Medisure packs were stored in cardboard boxes (commonly known as magazine files or file boxes). It was clear from the photographs that Mrs Forrest's were not while Mrs Frost's were. I have concluded that there is no particular significance to this. Mrs Harrison in her evidence made it clear that they had only just started this procedure and had only been sent so many boxes and were waiting for more to arrive. It was suggested to some witnesses by Mr Forrest that having the Medisure packs in such a box would provide a second check and might have prevented the accident but I have concluded that this is incorrect. It is the name and address on the actual Medisure pack being handed out that needs to be checked rather than the name

on the file box as, theoretically, the dispenser could have put the Medisure pack in the wrong file box anyway. The evidence suggested that the use of these file boxes was simply for ease of storage and to keep the Medisure packs tidy and in good order. It was clear from Dr Moss's evidence that matters such as this were left to each pharmacy to fix their own procedures. I attach no particular significance to the fact that the deceased's Medisure packs were not within such a box but were kept together on the shelf in an elastic band.

[23] Crown production 13 was noted as a "DDS book". This was a system introduced by the responsible pharmacist, Nichola Ferguson, and was not mandatory under Boots Standard Operating Procedures. It was apparent from the evidence of the Boots' employees and Dr Moss, that the purpose of this was primarily to provide an extra check if, for example, a patient was coming in too early or too late for their medication. Mrs Forrest had signed this book on two previous occasions, (on 24 and 31 October 2013) but had not signed it on the day when she must have picked up the medication meant for Mrs Frost. Witnesses were quite candid in saying that the book was usually completed but not always and was sometimes missed, particularly when they were busy. It was clear from the evidence that even if Mrs Forrest had been asked to sign the book on the day in question it would not have prevented the accident. It would probably have provided an audit trail to show which member of staff had actually handed over the wrong pack to her but would not have prevented the accident.

Section 6(1)(d)

[24] A significant part of the inquiry was devoted to hearing evidence on the Standard Operating Procedures employed by Boots UK Ltd ("SOPs"). There was detailed evidence from all members of Boots' staff in Kingussie who gave evidence, and from Dr Moss, in relation to the Boots SOPs. It was clear from all staff that they understood fully what the SOPs required them to do. It did appear, however, from their evidence that the SOPs were not always carried out to the letter, probably because it was a local pharmacy in a small community with regular customers who were well known by all those working in the pharmacy. All employees gave evidence that they would often know who it was without asking, when it was a regular customer such as Mrs Forrest who used to attend the pharmacy regularly even before she was prescribed her medication in Medisure packs.

[25] The error in this case appears to have happened at the handover stage. There was a failure by a member of staff to reconcile the name and address details of the patient with what was on the pack that was being handed over. A three-way check of those details is required and is outlined in the SOPs but that did not happen in this case. The check is outlined in the Boots Standard Operating Procedures 006 version 5 (Crown production 11 and appendix 4 to Dr Moss's report) and the steps are clearly laid out. The prescription should be physically in the employee's hand. The name and address should be checked. The bag/pack should be picked up and the name and address on the label should be checked with the prescription and then the employee should walk over to whoever is waiting for it and ask for the name and address of the patient they are

collecting for. If they cannot provide the name and address, the prescription should not be issued.

[26] Boots have introduced new Standard Operating Procedures specifically for Medisure pack prescriptions (SOP:DDS5 version 1) due to the increased number of Medisure packs being prescribed. However the same Standard Operating Procedures for handover/dispensing apply whether or not it is a Medisure pack or a normal prescription. Steps 1 – 4 are identical in both SOPs. If the Standard Operating Procedures in existence at the time had been followed, the accident would not have happened. Mr Forrest for the family submitted that there should be new SOPs specifically for elderly and vulnerable people. I do not consider that that is practicable. Age is not necessarily the determining factor. Who is to decide at what age someone should be deemed vulnerable? Any drugs which have the potential to cause harm as well as good if taken incorrectly or by the wrong person should be checked carefully and effectively whether they are being dispensed to an elderly person or to a young person. Having too many different SOPs is more likely to cause more confusion and potential for error than applying the same SOPs correctly. It was not the content of the SOPs which were at fault in this case, rather the failure to apply them.

[27] It is impossible for me to come to a conclusion, on the evidence, as to who made the error in handing the wrong pack to Mrs Forrest. Indeed, it is not necessary for me to do so. As stated earlier, it is not the role of a fatal accident inquiry to find fault but rather to find facts.

[28] Nikki Winter, now a dispenser and previously a dispensing assistant, gave evidence that she understood the SOPs and had been trained in them. She would now always confirm the name and address on the prescription and ask the patient to state the address. At the time of the incident she would not have asked the address if the customer was known to her. The entry in the DDS book of 30 October 2013 showed Nikki Winter's signature and that of Mrs Forrest. It also shows an arrow because she had initially entered it on the wrong date. It should have been entered on 31 October. Ms Winter identified the signature on 24 October as that of Julie Mossman, a relief pharmacist. She was unable to say who had handed the prescription over on the date in question.

[29] Joan Harrison also gave evidence that she was familiar with the SOP procedures. She had worked in the pharmacy for so long (21 years in total having worked for the previous owner before Boots took over) that she knew "everyone". She spoke to Mrs Forrest coming in every week. She would now not hand out medication without checking the address on the label. She could not remember if she had ever handed out a Medisure pack to Mrs Forrest. She was unable to say who had done so on the date in question.

[30] Eva Oden is now a dispensing assistant but was a healthcare assistant at the relevant time. Healthcare assistants could not dispense drugs but could hand out dispensed medication. She has been trained in SOPs. She remembered Mrs Forrest coming in on one occasion and sitting down in the waiting area waving her Medisure

pack in the air and wanting a refill. She thought that Nichola Ferguson had taken the old pack but was unable to say who had handed out the new pack.

[31] The incident was investigated by NHS Highland and a SBAR report (Situation, Background, Actions, Recommendations - Crown production 12) was produced. The NHS Southern and Mid Highland Head Pharmacist, Thomas Ross was content with the actions Boots had taken after the event, namely it having been emphasised to staff that the SOPs had to be carried out even if the patient was well known to them and that they should obtain the patient or representative's signature when uplifting the Medisure pack. The storage system for the packs had been amended to have them not all together in alphabetical order but in alphabetical order in batches by the date they were made up, and new SOPs for Medisure packs had been introduced. He was of the opinion that the completion of the DDS book in Kingussie had been over and above what was required of the staff by the existing SOPs. He gave evidence to the effect that the NHS had not made any recommendations to change the existing systems of working. In cross examination he also agreed with an extract from a letter from the General Pharmaceutical Council to the COPFS that "adequate measures had been put in place to address the error and prevent a re-occurrence" (Forrest family production no 3).

[32] Having heard all of the evidence I am satisfied that there was no defect in the actual system of working. Had the prescribed system been followed correctly the accident would not have happened.

Section 6(1)(e)

[33] Dr Jose Moss is a highly qualified pharmacist. She is the deputy superintendent pharmacist for Boots UK Limited. She has a detailed knowledge of the pharmacy industry and of the procedures operated by Boots UK Limited. While it is clear that she cannot be considered as a truly independent expert in the sense that she is employed by Boots UK Limited, I am satisfied that she gave her evidence in an honest, impartial and straightforward way just as one would expect from any expert witness. There was no contrary witness with her expertise called by any other party to the inquiry and I am satisfied that I can rely on her evidence in relation to the matters on which she gave evidence.

[34] There was a suggestion put forward by Mr Forrest on behalf of the family that Medisure packs which contained gliclazide should be coloured red. While this might have superficial appeal, it seemed to me that it was not practical or feasible. Self-evidently (and this was confirmed by Dr Moss in her evidence) there would be other drugs, just as dangerous as gliclazide to people who do not require them and complicating matters by having a number of different coloured packs would be likely to cause more confusion rather than less. What would happen if someone was prescribed two or three drugs which were deemed dangerous to others and were supposed to be put in different coloured packs? What colour would the pack have to be?

[35] Dr Moss was questioned at length about this. She took the view that it would not be practicable to do this. Gliclazide was very widely prescribed for a lot of people who need Medisure packs. There would be no guarantee that medication for two

patients needing red packs would not be beside each other. In addition, if the pharmacy ran out of red packs what would they do? There would then be pressure to have other medication in different coloured Medisure packs which could cause more confusion.

There could potentially be a patient with more than one high risk medication. There are numerous other drugs which would have similar bad effects on someone not requiring them, for example warfarin, rivaroxaban, morphine, pethidine, certain medication designed to lower blood pressure and even penicillin if someone is allergic to that. She was asked if someone were, for example, diabetic but also prescribed warfarin on top of gliclazide and a strong painkiller, how would the colour system work? She said it would not get rid of the risk. If one patient had gliclazide and two other drugs and one patient had gliclazide and four other drugs, patients could still get the wrong red pack.

[36] She also gave evidence that original packaging of medication is not controlled by Boots. The Medicines Healthcare Products Regulations Agency controls the packaging. They look at the packaging of medicines and the extent it could be contradictory with different coloured packages that already exist, which again might cause more confusion. A further objection to the red pack idea was that not all patients requiring gliclazide would need or get a Medisure pack and would just have the original pack with a label. So gliclazide could be being prescribed in 2 different coloured packs which could cause more confusion.

[37] It was suggested by both the Crown and the family of Mrs Forrest that getting the patient or representative who was uplifting the medication to read the address on the pack would be a suitable extra safeguard. I do not agree. It seems to be that

Medisure packs, by their nature, would generally be prescribed for elderly and/or vulnerable people or people requiring a considerable amount of medication. Some elderly patients may be unable to read the label properly when handed it in the pharmacy and may be inclined simply to agree with what the assistant said. The issue of data protection was raised by Dr Moss. The Crown suggested that this was not a real issue. In my view while obviously it would not be an issue if the correct pack is put to the person uplifting the medication, it would be an issue if the incorrect pack was put to them. In addition, and more importantly perhaps, this puts the onus on the patient/customer/representative not the staff which I do not consider would be helpful or indeed appropriate. The ultimate responsibility for checking the details on the pack must lie with the member of staff who is handing over the medication.

[38] There was a submission from the family that there was “clear evidence” that the pharmacy was understaffed at the time and that this played a part in the accident. In fact the only direct evidence that was heard in relation to the events on the day that the deceased picked up the Medisure pack that ought to have been given to Mrs Frost, was from Eva Oden and suggested that the pharmacy had been quiet at the time. It was certainly suggested by some witnesses that the DDS book was sometimes not completed if they were busy but as previously noted this would not have prevented the error happening; it would simply have provided an audit trail. It is not possible to say that just because the DDS book had not been completed then that meant that the pharmacy was necessarily understaffed on the day in question. It was clear from the evidence that Boots UK Limited have introduced a new DDS docket system around the country as a

result of the accident in Kingussie. This would be useful in providing an audit trail in the event of another error but would not actually prevent another similar error taking place in the first place.

[39] The family also submitted that there were failures in respect that the “quad stamp” on prescriptions had not been initialled by the dispenser. This was conceded by all relevant witnesses who gave evidence. The quad stamp is a circle with 4 quarters which are initialled at different stages in the dispensing and handover procedure (clinical check, accuracy check, dispensed and hand out). Again, it was clear from the evidence that this would not have prevented the accident happening but might have provided an audit trail. I would repeat again that it is not the purpose of this inquiry to apportion blame but rather to find facts.

[40] Finally, the family also submitted that all staff of Boots UK Limited, whatever their role within the organisation, should sign off that they are familiar with the General Pharmaceutical Council Standards for Registered Pharmacies. That document was produced and lodged by the family and some witnesses were referred to it. It was clear that the Boots staff from Kingussie who were questioned had not seen this document and were unable to comment on it but were familiar with Boots UK Limited’s own SOPs. Dr Moss gave clear evidence about what this document was, who it was intended for and what its purpose was and I had no reason to doubt her evidence on this matter. It was a document prepared by the General Pharmaceutical Council (the external regulatory body for pharmacy premises and pharmacy professionals practising in Great Britain). Registered pharmacists have to abide by these standards and are responsible

for that. They in turn ensure that they are met by the use of internal operating procedures such as the Boots UK Limited SOPs. The General Pharmaceutical Council has no power over non pharmacist grade staff within the industry and it would not be appropriate for non-pharmacist staff to have to assimilate or “sign off” on what is contained in their operating standards.

[41] Having considered all of the evidence and submissions put forward I am satisfied that there are no relevant facts which fall within the scope of this section. Nor are there any recommendations which I require to make.

Conclusion

[42] In conclusion, it appears that tragically Mrs Forrest was handed the wrong Medisure pack by an employee of Boots UK Limited in Boots pharmacy, High Street, Kingussie. This clearly should not have happened. Had process steps 1 – 4 of the Standard Operating Procedures 006 version 5 prepared by Boots UK Limited been correctly followed, this would not have happened and the accident and consequent death would not have taken place. It seems that the accident was as a result of human error, an error which has had tragic and catastrophic consequences.

[43] During the course of the inquiry, and at the end, I extended my condolences and those of the court to Mrs Forrest’s family, one of whom represented the family, others who gave evidence and sat through the rest of the inquiry and others who did not attend. I was joined in that by the procurator fiscal depute and Counsel who

represented Ms Ferguson and Boots UK Limited. I would wish formally to repeat those condolences in this determination.