

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN
DISCIPLINARY COMMITTEE

1 Lambeth High Street
London, SE1 7JN

Monday 5 January 2009

Chairman: Mr John Burrow

Case of:

IHSAN, Mohammed

Reg No: 80046

(Transcript of the shorthand notes of T. A. Reed & Co Ltd
Tel No: 01992 465900)

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Panel Members:

Mrs Joy Tweed
Mr Edward Mallinson

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MR TOM RIDER of Field Fisher Waterhouse appeared on behalf of the Society.

MR DAVID REISSNER instructed by Charles Russell, appeared on behalf of the respondent, who was present.

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A

THE CHAIRMAN: Good morning everybody. So we know where we are, this is the adjourned hearing from 5 November. On 5 November, we gave judgment in the case of Mr Guraewal and reserved the facts and the misconduct judgment in relation to Mr Ihsan. So this morning we will give judgment on the facts and misconduct in respect of Mr Ihsan.

Decision on the facts

B

THE CHAIRMAN: Mr Ihsan was first registered with the Society on 18 August 1986. In 2004 and 2005 he was the superintendent pharmacist and a director of Mojha Limited, the company which owned Haslucks Green Pharmacy at 130 Haslucks Green Road, Shirley, Solihull ('The pharmacy') and he was the regular pharmacist in charge.

C

Overview of the case

D

Patient MF was an elderly patient who had been taking Warfarin for many years. Warfarin is a powerful anticoagulant medication which can be dangerous, if taken in too large a dose. The dosage is determined by the patient attending an anticoagulant clinic every month or so, where her international normalised ratio (INR) level is determined. This is recorded in the patient's anticoagulant therapy record (ATR), also known as the yellow book. In that book is also recorded the current dosage of Warfarin. As the INR changes, so does the dose. A change can occur quite often, and indeed did so in this case. Warfarin is a medicine with an above-average risk in its use and special care is needed when dispensing it.

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In 2004, Patient MF's family became concerned about her ability to take her medication reliably and they contacted her GP to enquire about a monitored dose system (MDS). This is a system whereby specific daily doses are placed into blisters in a tray and sealed. Each blister is allocated for a specific time of a specific day, and the patient is expected to take the contents of the blister as indicated on the pack.

G

This system was set up for her at the pharmacy. The arrangement was that the surgery would write out prescriptions for the period, usually two weeks or a month. The prescriptions for Warfarin did not have a specific dose on them, merely to take "as per INR". Under the system it was for the pharmacy to ascertain what the dose was. They did this by arranging with the son of Patient MF to inform the pharmacy when there was a change in the dose of medication in the yellow book. The pharmacy then would request the specified amount of Warfarin from

H

A the surgery. The surgery would issue a prescription for the specified amount for the next monthly period, and the pharmacy would dispense at the new level in the MDS.

B It appears, however, that the son brought the yellow book into the pharmacy only once. The repeat prescriptions would be ordered by the pharmacy on the basis of the patient medication record (PMR); that is to say, what the patient had received previously. No check was made with the patient before ordering the repeat prescriptions, as stipulated in the Society's *Code of Ethics and Standards*. Further, no record was kept of what was ordered by the pharmacy from the surgery.

C From 13 August 2004, when the MDS began, to 14 January 2005, the Warfarin dose varied between 1mg a day and 3mg a day. Around 24 January 2005, the pharmacy received four prescriptions dated 19 January 2005. Two prescriptions were for 28 x 1mg tablets of Warfarin. Two were for 28 x 3mg tablets of Warfarin. It is not alleged that the pharmacy ordered the D Warfarin at these levels. It is not known how or why prescriptions at these levels were issued. Neither the surgery nor the pharmacy can give an explanation. The failure by the pharmacy to keep an audit trail of medicines requested has meant that it has not been possible to ascertain who requested the higher dose.

E The yellow book continued to state that the appropriate dose was 2mg a day. However, the amounts prescribed were consistent with a daily dose of 8mg, and this is what was placed in each daily blister of the MDS by the dispensing assistant. No inquiry as to why the doses had increased so much was made by the pharmacy, despite the care which should be exercised with F Warfarin and despite the previous dosage history at substantially less than this amount.

G Supplies were made to the patient from these prescriptions on this basis on 26 January 2005, 16 February 2005 and 23 February 2005. It was apparent that Patient MF was taking the Warfarin at this higher level for at least part of this period. She banged her arm and suffered internal bleeding, which was greatly exacerbated by the overdose of Warfarin. She was admitted to hospital, contracted MRSA, was operated on and sadly died. The overdose of Warfarin was specified by the Coroner as one of the causes of death.

H Mr Ihsan was responsible for checking on 15 February 2005 and 22 February 2005 the supplies of Warfarin made on 16 and 23 February 2005, and he now faces a number of allegations in

A respect of this. It was alleged that Mr Guraewal, his business partner, was responsible for checking the supply which was made on 26 January 2005. The Society was unable, on the evidence, to prove that the check made in respect of this supply was made on 25 January 2005 when he was on duty, and the case was dismissed against him.

B

The burden and standard of proof

C The burden of proving the allegations of fact, the breaches of the Code of Ethics and Standards and of proving misconduct, lies upon the Society. The standard of proof of the allegations of fact is the civil standard. Before a finding of misconduct which renders the respondent unfit to have his name on the register may be made, there must be serious misconduct, or misconduct that is more than merely negligence.

D

The allegations

The first allegation

E (the numbering is that of the Notice of Inquiry) Paragraph 4(a)
It was alleged that in or around the first half of January 2005, the pharmacy submitted a request for repeat prescriptions of medication from Patient MF, including for Warfarin, to her GP surgery.

F This allegation was admitted by Mr Ihsan and we found it proved on the balance of probabilities.

Paragraph 4(b)

G It was alleged that in or around the first half of January 2005, Mr Ihsan did not have procedures in place at the pharmacy for:

- (i) Establishing with Patient MF, or her carer or family, in advance of making the request whether Warfarin was still required and, if so, at what dosage.

H This allegation was admitted by Mr Ihsan, but he said it would not be usual for the

A pharmacist to know the dose. He said the arrangement was for the family to contact the pharmacy, but he accepted that this only apparently happened once during the period the pharmacy was supplying the MDS to Patient MF. We found the allegation proved on the balance of probabilities.

B It was alleged that these matters were in breach of paragraph 6 (e) of Part 3 of the Code of Ethics and Standards. This states: “*At the time of each request the pharmacist must establish items the patient or their carer considers are required and ensure that unnecessary supplies are not made.*”

C Mr Ihsan denied that he had breached this section of the Code. He argued that the section was not intended to prevent errors in the supply of medicines, but merely to prevent unused supplies of unnecessary medicines building up at a patient’s home. When this was put to the Society Inspector, she denied it, saying its principal aim was to prevent errors in supply. We D accepted this evidence.

In interview, Mr Ihsan appeared to accept that if an inquiry had been made of the family the errors could have been avoided. In cross-examination, Mr Ihsan accepted that this part of the Code was not followed in the case of Patient MF. He said in interview that he was not aware E of the guidance in the *Medicines Ethics and Practice* requiring the pharmacist to establish what items are required. We accepted that the failure to ascertain the dosage of Warfarin required was a serious failure and was more than mere negligence. As set out above, Warfarin is a F medicine which requires special care in its dispensing. The level of Warfarin can change regularly. To leave the initiative with the patient to notify changes in dose to the pharmacy was not reliable or sufficient. This is particularly the case where the medicine is supplied by means of an MDS, where there is a presumption that the patient is expected to take the whole dose from a blister. The Code places the responsibility on the pharmacist to establish the G required dosage. We accepted that there had been a breach of this section of the Code, and as set out above we considered the breach was a serious one and constituted misconduct which renders Mr Ihsan unfit to be on the register.

And

H **paragraph 4(b)(ii)**

Ensuring that an audit trail existed to identify and keep a record of what medication, including

A Warfarin, had been requested.

This allegation was admitted by Mr Ihsan. Repeat prescriptions were ordered by the dispensing assistant by dispatching the repeat prescription section of the prescription, filling it in and sending it to the surgery. No copy of this document was kept at the pharmacy, and the repeat prescription form was not generally returned to the pharmacy. Mr Ihsan admitted in cross-examination that this was the system which was used, and we found it proved on the balance of probabilities.

It was alleged that this was breach of paragraph 6(a) of Part 3 of the Code of Ethics and Standards, which states: *“The pharmacy must operate a patient medication record (PMR) system, notified to the Information Commissioner and ensure that an audit trail exists to identify each request and supply, so as to enable the service to be monitored.”*

This breach was admitted in Mr Ihsan’s cross-examination and apparently admitted in his statement of case. The professional responsibility to keep an audit trail of medicines requested is an important one, particularly with a higher risk medicine such as Warfarin, where regular reviews may be necessary. We accepted that a failure to maintain an audit trail in the circumstances was a serious matter going beyond mere negligence. The failure by the pharmacy to keep an audit trail of medicines requested has meant that it has not been possible to ascertain who requested the higher dose. We accepted there was a breach of the Code.

For the reasons set out above, we regarded the breach as a serious one which renders Mr Ihsan unfit to be on the register.

The second allegation

Paragraph 5

It was alleged that on or about 24 January 2005 the pharmacy received from Patient MF’s GP surgery four prescriptions for patient MF: Two each for Warfarin 28 x 1mg tablets, and two each that included Warfarin 28 x 3mg tablets when

- a) the pharmacy’s patient medication record for Patient MF showed her then current medication to be 1mg Warfarin tablets taken twice daily.

A This allegation was admitted by Mr Ihsan. We found the allegation proved on the balance of probabilities. **And (b)**

The daily dose recommended for her by an anticoagulant clinic was 2mg Warfarin.

B This allegation was admitted by Mr Ihsan, but he said the dose would not normally be provided to the pharmacist, and it was not reasonable to expect him to know it. This was not accepted by the Society, as it was not consistent with the pharmacist's duty under paragraph 6(e) of Part 3 of the Code to establish requirements at the time of each request. We found the allegation proved on the balance of probabilities.

C **The third allegation**

Paragraph 6(a)

D It was alleged that on or about 15 February 2005, Mr Ihsan checked a compliance pack prepared by the pharmacy for Patient MF that included 7 daily doses of 8mg Warfarin, comprising 2 x 1mg and 2 x 3mg Warfarin tablets, and he failed to undertake a professional assessment of the prescriptions in relation to Warfarin given

E i) the matters set out at paragraphs 5(a) and (b) above, and
ii) the daily dose recommended for her by an anticoagulant clinic continued to be 2mg Warfarin.

F This allegation was denied in Mr Ihsan's statement of case. He did admit carrying out the check for this supply. He said in the statement of case and in his evidence to the Committee that he had checked the patient's history on the PMR and had carried out a professional check. He said he could not reasonably be expected to know the daily dose recommended by the Warfarin clinic. He admitted that he had said in interview with the Society Inspector that the checking was normally done without reference to the PMR and that the system was not foolproof. In resolving these two conflicting accounts we accepted, on the balance of probabilities, the account given in the interview, as it was nearer the time of the incident and was his first explanation. We accepted therefore that he had not checked the PMR when carrying out the purported professional check during the dispensing process.

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A He said the 8mg dose was within the accepted maintenance dose as outlined in the BNF, but we noted that a range of doses may be within the maintenance dose, and therefore acceptable only on a generalised basis. The important thing was to ascertain the specific dose which was correct for the patient. This was the purpose of testing the INR at the clinic and setting the appropriate dose.

B It was also pointed out by the respondent that in October 2003, an 8mg dose had been prescribed. However, we noted that this was for two days only, after which it was substantially reduced to 3mg a day.

C Mr Ihsan accepted that since August 2004 the patient had not received more than 3mg a day. Mr Ihsan admitted that it was an error of judgment on his part to process a supply of 8mg a day and let it through. He agreed that the prescription was marked “as per INR”. He agreed that at the time of the checking he could not be sure of the dosage. He accepted that he did not know what had been requested because no record was kept. He knew there had not been any check with the patient to establish what the recommended dose was. As set out above, he did not check the PMR at the time the professional assessment should have been done. Mr Ihsan admitted that he had failed to make sure whether that actual prescription was needed. Mr Ihsan pointed out that even if he had checked the PMR, he would have found two recent entries which referred to 1mg and 3mg tablets of Warfarin, suggesting an 8mg daily dose.

E However, we concluded that a professional assessment in the circumstances of this case involving, as it does, the higher risk nature of the medication and the prescribing history of the patient, he should have satisfied himself that the much larger dose over a period of several weeks was appropriate for patient MF. The Society said that had Mr Ihsan checked with the patient or the patient’s carer as to her required needs for Warfarin, then he would have known what the required dose was and the error could have been avoided.

F In these circumstances we found the allegation that Mr Ihsan had not carried out a professional check, proved on the balance of probabilities.

G It was alleged that this was in breach of paragraph 4(1) b of part 3 of the Code of Ethics and Standards, which states: “Every prescription must be professionally assessed by a pharmacist to determine its suitability for the patient. The pharmacist must ensure that the patient receives sufficient information and advice to enable the safe and effective use of the medicine.”

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A We again noted the higher risk nature and the commensurate care needed in the supply of Warfarin. A failure to carry out a professional assessment was, in our view, a serious matter going beyond mere negligence. We accepted that there had been a breach of the Code and that the matter were so serious that it rendered him unfit to be on the register.

B (b) It was alleged that a compliance pack including 7 daily doses of 8mg Warfarin, comprising 2 x 1mg and 2 x 3mg Warfarin tablets was delivered by the pharmacy to Patient MF's home on or about 16 February 2005.

C This allegation was admitted by Mr Ihsan and we found it proved on the balance of probabilities.

Fourth allegation

Paragraph 7(a)

D It was alleged that on or about 22 February 2005, Mr Ihsan checked a compliance pack prepared by the pharmacy for Patient MF that included 7 daily doses of 8mg Warfarin, comprising 2 x 1mg and 2 x 3mg Warfarin tablets and he failed to undertake a professional assessment of the prescription in relation to Warfarin given

- E
- (i) the matters set out in paragraph 5(a) and (b) above; and
 - (ii) the daily dose recommended for her by an anticoagulant clinic continued to be 2mg Warfarin.

Paragraph 7(b)

F A compliance pack, including 7 daily doses of 8mg Warfarin, comprising 2 x 1mg and 2 x 3mg Warfarin tablets was delivered by the pharmacy to Patient MF's home on or about 23 February 2005.

G This is a similar allegation as allegation 3 above, albeit relating to a supply on a different day. The same or similar arguments were deployed by Mr Ihsan in respect of the third allegation as in respect of this allegation. He denied the allegation. For the same reasons as in respect of allegation 3 above, we found the allegations proved on the balance of probabilities.

H It was alleged that this was in breach of paragraph 4.1. (b) of Part 3 of the Code of Ethics and Standards, which states: "Every prescription must be professionally assessed by a pharmacist

A to determine its suitability for the patient. The pharmacist must ensure that the patient receives sufficient information and advice to enable the safe and effective use of the medicine.

We found a breach of this section of the Code for the same reasons as for allegation 3 above, and we found the misconduct was so serious it rendered Mr Ihsan unfit to be on the register.

B Fifth allegation.

C Paragraph 8. It was alleged that in the period between 24 January and 23 February 2005, Mr Ihsan did not ensure, as superintendent pharmacist, that a retrievable record of the pharmacist taking responsibility for the provision of each pharmacy service was maintained, and that an identifiable pharmacist was accountable for all activities of non-pharmacists involved in the provision of pharmacy services, in that he did not give clear instructions to pharmacists working at the pharmacy that they should at all times initial and check all medication containers.

D Mr Ihsan denied this allegation. He said that he had been away on a pilgrimage to Mecca between about 6 January and 2 February 2005. He had left the running of the pharmacy in the hands of his fellow director, as he was entitled to do under the principle of *R v The Statutory Committee of the Royal Pharmaceutical Society of Great Britain, ex parte Lewis and Jeffreys limited* QBD (unreported) 20 November 1982.

E However, he said in interview with the Society Inspector that he had not given clear instructions to pharmacists to initial the boxes. He said the pharmacy had recently introduced the labels and he said: “We were not in the habit of signing them.” He could not recall whether the signing of boxes was in the SOP.

F In cross-examination, Mr Ihsan accepted that there was no retrievable record of who took responsibility for a particular pharmacy service, namely checking the supply of medication. He accepted that in respect of an MDS supply, where the label printing, the checking and the supply may be on different days, the PMR, (which showed the day the label was printed), together with the duty rota did not give adequate information to ascertain who had checked the supply. It was because of this failure that it was not possible, for instance, to ascertain who had made the supply on 26 January 2005. We accepted that on the basis of his admissions in interview Mr Ihsan knew that pharmacists were not habitually signing the “checked by” boxes, and that he had left the pharmacy without giving clear instructions to sign the boxes. This was

A in distinction to the case of Lewis and Jeffreys, where full and clear instructions to comply with professional responsibilities had been given. We accepted that the allegations had been proved on the balance of probabilities.

B It was alleged that this was contrary to paragraph A2a and d of Part 2 of the Code of Ethics and Standards. Paragraph A2a states: “*Superintendent pharmacists have a personal and professional responsibility to ensure the observance of all legal and professional requirements in relation to pharmaceutical aspects of the business. They are responsible for ensuring that a retrievable record of the pharmacist taking responsibility for the provision of each pharmacy service is maintained and that an identifiable pharmacist is accountable for all activities of*

C *non - pharmacists involved in the provision of pharmacy services.*”

We accepted that this was a serious breach of the Code, for the reasons set out above, going beyond mere negligence, which had led *inter alia* to the inability to determine who was responsible for checking the supply made on 26 January. We accepted that there had been a

D breach of this part of the Code, which was so serious that it rendered Mr Ihsan unfit to be on the register.

Paragraph A2d states: “*To ensure all staff are informed of the professional activities they are expected to undertake. Clear instructions should be provided designed to identify and*

E *minimise risks and reviewed regularly. Where possible standard operating procedures should be drafted.*”

In view of Mr Ihsan’s admissions in interview, we accepted that clear instructions had not been

F given. This was a serious failure going beyond mere negligence, for the same reasons as set out above, and we accepted that there had been a breach of the Code.

It was further alleged that the actions as set out in respect of the five allegations above were in breach of Key Responsibility 1 of the Code of Ethics and Standards.

G This matter was admitted by Mr Ihsan during cross-examination. There is no allegation that the pharmacy requested the wrong dose of Warfarin. However, Warfarin is a powerful higher risk medicine which requires particular care in its dispensing and supply. The failures set out above resulted or contributed to the tragic circumstances of Patient MF’s death. The Coroner found the overdose of Warfarin was one of the causes of death and referred to an

H “inappropriate pharmacy dispensing system”. It may be that there was no guidance at the time

A or since forbidding absolutely the use of MDS for the supply of Warfarin, but a number of serious errors were made. The Coroner said MDS supply should not be used for any medicine where the dose is variable.

B We accepted that errors were serious and amounted to more than mere negligence, that the key responsibility had been breached and that Mr Ihsan was guilty of such misconduct as to render him unfit to be on the register.

C By reason of the number and seriousness of the breaches set out above, we concluded individually and cumulatively they rendered Mr Ihsan unfit to have his name on the register.

That is our determination as far as facts and misconduct are concerned.

Approved as amended by Mr John Burrow on 12 January 2009

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A

DETERMINATION ON SANCTION

B

THE CHAIRMAN: We retired to consider sanction. We have had regard to the Society’s sanction guidance document. We bore in mind that the purpose of sanction was not primarily to punish or further punish the registrant. The purposes of sanction are threefold. Firstly, the protection of the public; secondly, maintenance of public confidence in the profession; thirdly, the maintenance of proper standards of behaviour. We also bore in mind that any sanction must be fair and proportionate, in the sense that the sanction is no greater than is absolutely necessary to achieve its objectives.

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D

We first considered whether there were aggravating factors in the case and we found three. Firstly, there was here a vulnerable victim. Patient MF was aged 85 at the time, with a number of serious medical conditions. Secondly, there was actual injury to the patient, who sadly died. Dr Jones, Professor of Pathology, carried out the autopsy and he found that one of the actual causes of death was the Warfarin therapy. The Coroner said he did not find a gross failure by any one person, but he also referred to “an inappropriate pharmacy dispensing system, which had combined with a series of missed opportunities to turn a minor accident into a fatal event.” Thirdly, we found there was misconduct committed by Mr Ihsan when he was a person in charge on pharmacy premises. We did consider a fourth factor, as to whether misconduct was sustained or repeated over a long period of time. We noted that misconduct included a systemic failure to establish items the patient or their carer required. Mr Ihsan said in interview that he was at the time not even aware of this requirement. There were also failures to carry out a professional assessment on two occasions. Also, there was a period of a month between 24 January 2005 and 23 February 2005, when he failed to ensure a retrievable record of a pharmacist taking responsibility for the provision of a pharmacy service. So while we did find that it was the case that misconduct occurred on more than a single isolated incident, as referred to in the mitigating factors section of the guidance document, we did conclude on the evidence that we could not say misconduct was sustained or repeated over a long period of time.

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We considered the mitigating factors. We received testimonials from five persons, including the practice manager of the doctor’s surgery who had worked with Mr Ihsan, an accountant, a bank manager (who is a patient), the Chief Executive of Holbrooks Health Team and a pastor who has knowledge of Mr Ihsan through a patient participation group. Mr Ihsan is described as proactive,

A caring, extremely thorough, providing an exemplary service, being very supportive, honest and trustworthy. He was said to be mortified by these events and he has indeed apologised to us for them. The pastor, who is a member of the patient participation group, emphasised the professional way in which Mr Ihsan conducts his business.

B Other mitigating features are the admissions made by Mr Ihsan when first interviewed. He admitted many of the allegations. He admitted, for instance, being the pharmacist who had carried out the checks on two occasions on 15 and 22 February. It is right to say, however, that he denied a number of the alleged breaches of the Code, which were subsequently found proved against him. However, we further notice there had been a lapse of nearly four years since these matters occurred. There has been no repetition of the misconduct since that time. Neither had there been any other appearances before the Statutory Committee in his 22 years as a pharmacist.

C We were also shown steps that he had taken to ensure there will be no repetition of the misconduct. D He has introduced standard operating procedures, covering the dispensing of Warfarin, which provided for adequate and proper contact with the patient or carer to determine the actual dose of Warfarin required. SOPs also provided that normally Warfarin would not be dispensed in MDS trays. Other SOPs provided for a professional assessment and for an audit trail of what medication is required. We further heard evidence that a retrievable record of the supply of medication is now in force.

E We concluded that despite the fact that some of the alleged breaches of the Code had been unsuccessfully challenged, Mr Ihsan had demonstrated, by the misconduct-free lapse of time and the new procedures put in place, that he has shown insight and is safe to practise without future risk to the public.

F We next considered the factors where the guidance document indicates a reprimand may be appropriate. As already covered, we accepted that there was evidence of insight and no continued risk to patients or public. We considered whether the misconduct amounted to minor breaches of guidance issued by the Society. We concluded that the misconduct was significantly more serious than this. Mr Ihsan was dispensing a higher risk medicine without making himself aware of the Society's Code requiring him to contact the patient. He had failed to ensure an audit trail was kept of medication which had been requested. He had failed to carry out a professional assessment in respect of a higher risk medicine. Taken together, we accepted that these matters in our view

A represented a significant failure in professional responsibilities which could not properly or proportionately be met by a reprimand.

B We considered the guidance document section headed ‘Where removal from the register may be appropriate’. We have dealt with many of these factors above and have found that there was no continuing risk, and that there is no suggestion of a current lack of competence.. However, on the issue of the misconduct being so serious as to undermine confidence in the profession, we bore in mind the fact that there had been a number of serious professional failures by Mr Ihsan which had contributed to the death of Patient MF, a vulnerable patient. It was true that the Coroner had said that there was no gross failure by any one person. But it is also true to say that he had referred to an inappropriate pharmacy dispensing system.

C It is also true that two of Mr Ihsan’s patients at least have supported him. We further noted that there was little professional guidance at the time specifically on the dispensing of Warfarin in MDS trays. It is apparently the case that no other healthcare professional has been the subject of disciplinary proceedings arising from this matter. We noted in particular that the MDS system was requested by the GP surgery following an inquiry by the relatives of the patient. It is true also that there has been a delay of some four years in concluding these disciplinary proceedings.

D However, we concluded that cumulatively the misconduct and its consequences were so serious as to undermine confidence in the profession, and we concluded that the fair and proportionate sanction in the case was removal. However, in all the mitigating circumstances of the case, we concluded that it would be right to allow Mr Ihsan to apply for restoration in 18 months. That is our decision.

E Are there any other matters either party wish to raise? (None) Gentlemen, thank you once again for your help.

Approved as amended by Mr John Burrow on 6th January 2009

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