

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN
DISCIPLINARY COMMITTEE

Tuesday 6 April 2010

1 Lambeth High Street
London, SE1 7JN

Chairman – Mr John Burrow

Case of:

CARRAMOLINO, Yolanda Monreal (1091007)

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

T A REED & CO LTD

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Panel Members:

Mr E Mallinson (Professional)
Mrs J Tweed (Lay)

Case of

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Ms Carramolino was present and represented by Ms Sandhya Kapila, of NPA.

Ms Lisa Davis, of the Royal Pharmaceutical Society of Great Britain, appeared on behalf of the Society.

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A

DETERMINATION ON FACTS, MISCONDUCT AND IMPAIRMENT

THE CHAIRMAN: Ms Carramolino is aged 34, Spanish by nationality. She qualified as a pharmacist in Spain in 2004, and completed a Masters degree in 2005. She was recruited in Spain by Boots Alliance in about July 2006, and having registered with the Society on 2nd November 2006, thereafter received training for some eight weeks, from Boots Alliance. Thereafter she worked for the company as a relief pharmacist with several pharmacies in and around the Hull area.

B

On Saturday, 5th May 2007, Ms Carramolino was the sole pharmacist in charge at Boots the Chemist at 232 Beverley Road, Hull in North Humberside. On that day the pharmacy received a delivery of medication which included Oramorph Unit Dose Vials 100mg/5ml. She failed to enter this medicine in the pharmacy's Controlled Drugs Register, even though at that strength it was a controlled drug. She thereafter supplied this medication to Patient BE against a prescription calling for Oramorph Oral Solution Unit Dose 10mg/5ml. In effect, the supply was at some 10 times the strength called for by the prescription.

C

It is alleged that this supply was in breach of Section 58(2) of the Medicines Act 1968, which states:

D

"No person shall sell by retail, or supply in circumstances corresponding to retail sale a medicinal product of a description, or falling within a class, specified in an order under this section except in accordance with a prescription given by an appropriate practitioner."

E

We noted that this supply was not in accordance with the prescription and we accepted that there had been the breach of Section 58. It is right to say that Ms Carramolino admitted this breach.

It was further alleged that these actions were in breach of Section 64(1) of the Medicines Act 1968, which states:

F

"No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser."

We accepted that the medicine supplied at 100mg/5ml dose was not of the nature or quality demanded and that there had therefore been a breach of this provision. Ms Carramolino admitted this matter also.

G

It was further alleged that her actions were in breach of Regulation 19(1)(a) of the Misuse of Drugs Regulations 2001, which states:

H

"Subject to paragraph (3) of regulation 21 every person authorised by or under regulation 5 or 8 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements, that is to say:

A (a) he shall, in accordance with the provisions of this regulation and of regulation 20, keep a register and shall enter there in chronological sequence subject to sub paragraph (f) using the heading specified in sub paragraph (d) and (e) particulars of every quantity of drug specified in Schedule 1 or 2 obtained by him and of every quantity of such a drug supplied (whether by way of administration or otherwise) by him whether to persons within or outside Great Britain."

B We accepted that the medicines, which as stated was Oramorph, were controlled drugs and had not been entered in the Controlled Drugs Register when delivered to the pharmacy, and that this provision had been breached. Ms Carramolino also admitted this breach.

C It was further alleged in the particulars of allegation that on 4th October 2007 at Queens Garden Police Station Ms Carramolino received a caution for the criminal offence of over dispensing a controlled drug and failing to complete the Controlled Drugs Register, in that on 4th October she admitted these matters.

D However, there appeared to be a technical error in the statutory provision said to have been breached in the caution procedure, and the Society did not seek to rely on the caution for the purposes of these disciplinary proceedings. We accepted the argument of the Society and we deleted the matter from the particulars of allegation, and did not rely any further upon it.

E The facts of this matter are that Patient BE, who was born on 25th May 1939, suffered from ill health for much of her life. She suffered from asthma when young and used a Ventolin inhaler. She developed chest infections which necessitated stays in hospital and she required steroids and antibiotics for these infections. In the last two years of her life her condition worsened and she struggled with her breathing. She was diagnosed with Chronic Obstructive Pulmonary Disease which required her to use oxygen, initially for some 16 hours a day but later for the whole day. Patient BE also suffered from bronchitis.

F After a hospital admission which ended in January 2007 Patient BE indicated that she did not wish to be admitted to hospital again. A palliative care package was developed for her, which included the attendance of a long term nurse to assist her with self-care and provide respite attendance.

G In the two week period prior to her death her long term nurse stated that he noticed a decline in her condition. On 4th May 2007 there were discussions about this decline with her GP, who subsequently issued a prescription for Oramorph at the 10mg strength, that is to say 10mg/5ml with 2.5ml to be taken every four hours as needed. This was part of her palliative care.

H Mr E, Patient BE's husband, took the prescription to the pharmacy on Friday 4th May 2007 to be dispensed. Ms Carramolino was not on duty on that day. The pharmacy did not have the medicine in stock and it was ordered for delivery the following day. Unfortunately the pharmacy technician, and again it should be stressed not Ms Carramolino, when entering the order into the pharmacy computer printed the label at

A | the wrong strength, namely the 100mg strength, not the 10mg dosage required by the prescription. The label was printed and the order was made at this increased strength, and the prescription and the label were placed to one side overnight to await delivery of the medicines the following day.

B | On 5th May 2007 the medicine at the increased strength was delivered, along with other medicines. Ms Carramolino was the sole pharmacist in charge of the pharmacy on that day. According to her account given to the police in her interview on 24th August 2007 the order arrived at about 10 o'clock. It included the Oramorph at the 100mg strength. At that strength, as we have said, it is a controlled drug and should have been entered in the Controlled Drugs Register and placed in the locked Controlled Drugs Cabinet. There was, in fact, a second controlled drug in the delivery, that is to say, Physeptone, which was entered in the Controlled Drugs Register by Ms Carramolino.

C | However, she said she misread the strength of the Oramorph, thinking it was 10mg and not the 100mg strength which had been delivered. At 10mg the medicine is not a controlled drug and would not have had to have been entered into the Controlled Drugs Register, or placed in the locked Controlled Drugs Cabinet. She said that she did not enter it into the Controlled Drugs Register for that reason.

D | It was not placed in the Controlled Drugs Cabinet because she said it was still waiting to be sorted when Patient BE's husband came in to pick the medicine up at about 10.30 that morning. It seems that Ms Carramolino prepared and dispensed the prescription so that she initialled the "dispensed by" box on the label. The medicine was dispensed directly from the unsorted medicine. She was also responsible for checking the accuracy of the medicine supplied against the prescription as she was the sole pharmacist in charge on the premises.

E | She failed to notice the discrepancy and when she was asked why she had failed in this respect in her interview she said, "I don't have any explanation for my mistake." She was asked again later in the interview, "Is there some reason why you missed the difference? Take your time. Like I said, it is difficult being in the interview room. If you can't think of an explanation that is fine." She replied, "I'm sorry. I have no explanation for it."

F | Patient BE's husband returned home to his wife with the medication. He gave two of the doses at 100mg strength on the 5th May at four hourly intervals. At that time, needless to say, he had not noticed the error in the dosage. Patient BE's husband said that his wife remained in fairly good spirits during the day, but a doctor who visited her at about 10.30 on 5th May described her as slightly breathless and cold. She had a chesty cough and was diagnosed with an infection and exacerbation of the COPD, and was prescribed a supply of Amoxicillin.

G | Patient BE's husband tried to administer a third dose of the Oramorph on Saturday, 5th May, in the evening, which she vomited and could not keep the medicine down. On 6th May 2007 in the morning Patient BE's husband attempted to administer a fourth dose of the Oramorph, but again Patient BE could not keep it down.

H |

A She was visited by a doctor at about 10.30 and her long term nurse, and the error of the Oramorph medication was finally spotted, and Patient BE's husband was told not to administer any further doses. Sadly, later that day, at about 2pm, Patient BE died.

B The post-mortem stated that the main findings were bronchopneumonia with severe emphysema and right ventricular hypertrophy. The Coroner commissioned a toxicology report to consider the administration of the overdose of the Oramorph. In his narrative verdict the Coroner stated:

"The primary cause of death was bronchopneumonia due to COPD. Shortly before her death she consumed a large dose of Oramorph following a prescription error. It is possible that this may have hastened to some extent her death."

C On this evidence, and on the admissions by Ms Carramolino and pursuant to Rule 35(2)(e) of the 2007 Rules we found the allegations set out in the particulars of allegation proved on the balance of probabilities.

D We then turned to consider the allegation of misconduct. We noted that there was a single dispensing error and that Ms Carramolino had been responsible for the dispensing as well as the checking in respect of it. We noted the medicine dispensed was a controlled drug requiring particular care. We noted that there had been breaches of the three statutory provisions, Sections 58 and 64 of the Medicines Act and Regulation 19 of the Misuse of Drugs Regulations 2001, and that there had been a failure to dispense in accordance with the prescription, a failure to supply a medicine of the correct nature and quality, and a failure to comply with the provisions relating to the Controlled Drugs Register.

E Misconduct was admitted by Ms Carramolino and we found it proved.

We then went on to consider whether Ms Carramolino's fitness to practise is currently impaired by reason of the misconduct we have found proved. We had regard to the principles set out in the well known cases of Zygmunt v GMC, Cheatle v GMC, Yeong v GMC, Azzam v GMC, and Saha v GMC.

F We accepted that we must have regard to the effect of the misconduct we have found proved looking forward, and to Ms Carramolino's practice before and after the misconduct. We accepted further that not all findings of misconduct necessarily entails impairment of fitness to practise.

G We accepted that we must have regard to whether the misconduct is an isolated error or whether it is a breach of the fundamental tenants of the profession and whether it can be remedied, or can be easily remedied. We must have regard to the remedial steps taken and whether the misconduct has in fact been remedied. We must have regard to insight and whether the misconduct is likely to be repeated. We must further have regard to whether the profession had been brought into disrepute and the reputation of the profession damaged. So we had regard to all these matters and all the principles spelled out in the cases named above.

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A | We first had regard therefore to Ms Carramolino's practice before and after the misconduct in May 2007. She had practised for only some four months before the error and had practised for only approximately another three or four months after it before returning to Spain in October 2007. There are no suggestions of any errors during either of those periods and thus the error on 5th May 2007 is an isolated incident, albeit in a relatively short period of practice.

B | We then considered whether the misconduct was remediable, and we accepted that despite the error being a breach of a fundamental tenant of the profession, that is to say the requirement of accurate dispensing, we accepted that the error was remediable.

C | We then considered whether the error had been remedied. We accepted that once Ms Carramolino had become aware of the error she wrote down, she told us, and analysed what had happened. She told us that as a result of this process she determined that she must take more care in the accuracy of her dispensing and that she whenever she dispensed she thereafter checked her accuracy two or three times, by checking the medicine dispensed against the prescription and the label.

D | We were somewhat concerned that she had not analysed the reasons for the error perhaps as thoroughly as she could have done, for example by considering the effect of dispensing directly from the unsorted medicine. We felt also that she might have taken further steps to provide reassurance that such an error would not happen again, including reference to the Standard Operating Procedures and a voluntary reference to the CPD training provisions. But we did accept that she had taken the incident extremely seriously; that she had focused her mind on the necessity for accurate dispensing and had genuinely learnt lessons from the incident and was now safe to practise.

E | We also took into account the three references she had provided. These were from two pharmacy colleagues in Boots at the time of the incident, including the District Pharmacy Manager, and a Spanish pharmacy colleague who worked with her in her current occupation as a clinical research assistant. She was described as displaying organisation and accuracy, was reliable, hard working, conscientious and highly motivated. She was said to be meticulous, to have perfectionism, to be accurate and responsible. We felt therefore that a repetition of the misconduct was not likely in these circumstances, and we further accepted that in terms of risk to the public from dispensing errors her fitness to practise was no longer impaired for that reason.

F | We then had regard to impairment through bringing the profession into disrepute and harming the reputation of the profession. We had regard to the serious consequences for Patient BE, who had been administered, or an attempt had been made to administer some four overdoses of a controlled drug at 10 times the prescribed strength. We also had regard to the Coroner's findings that it was possible that this may have hastened the patient's death. We accepted that the public rightly expect pharmacists to dispense medicines accurately and that where controlled drugs are concerned particular care is required and expected in their dispensing and supply.

H |

A | We concluded that in our judgment the impairment of the reputation of the profession was such that it still persisted and that for this reason Ms Carramolino's fitness to practise is currently impaired.

B | **DETERMINATION ON SANCTION**

C | THE CHAIRMAN: We retired to consider sanction. We reminded ourselves that the purpose of sanction is threefold: protection of the public, the maintenance of public confidence in the profession and the maintenance of proper standards of behaviour. It is no function of sanction merely to punish or further punish the Registrant. Any sanction we impose must be fair and proportionate and impose no greater restriction than is absolutely necessary to achieve this effect.

D | We had regard to the Society's Indicative Sanctions Guidance booklet and to the "Aggravating Features" heading set out therein. We found three such aggravating features. Firstly, we found that there was here a vulnerable victim, a lady aged 67 who had been suffering from chronic ill health. We secondly found that possible actual harm had been caused to the victim. Finally, we found that the misconduct was committed whilst Ms Carramolino was the person in charge of the pharmacy premises.

E | We then had regard to mitigating features, and we found two. First, this was a single isolated incident, albeit it should be said that this was not in a long career, but that there was a relatively brief period of practice up to the time of the incident. We further accepted there had been full and frank admissions at an early stage, and that Ms Carramolino had shown insight into her misconduct.

F | We also had regard as mitigating features to the three character references which we have set out above, in respect of which we specifically reminded ourselves of their effect in considering sanction.

G | We then had regard to the section of the Indicative Sanctions Guidance which considers those matters which might suggest a particular sanction. We considered the least serious sanction first, so we considered initially those cases where a warning may be appropriate. We have noted above that there is in our judgment no continuing risk to patients or public from Ms Carramolino's practice. We have further accepted that Ms Carramolino has shown insight into her misconduct and has taken remedial steps in respect of it.

H | Finally, we considered whether the misconduct committed constituted a minor breach of the guidance issued by the Society. Whilst we have characterised the misconduct as being serious in some respects, particularly in its consequences, we have found that Ms Carramolino does have insight, and that there is no future risk from her practice, and we have found impairment solely on the basis of impairment of the reputation of the profession. We felt that any proportionate and fair sanction must fully reflect these findings.

A Further, we noted that no breach of the Society's guidance was either alleged in the notice of allegation, or found as a fact by ourselves. In these circumstances we accepted that the fair, appropriate and proportionate sanction was a warning, pursuant to Article 52(3)(a)(i) of the 2007 Order, which states as follows:

"You must have full regard to compliance with systems for safe dispensing of medication, and continue to be vigilant in your checking procedures."

B The details of this order shall be recorded on the Registrant's entry on the Register and of course Ms Carramolino will be notified of this decision in writing in due course. That is our finding.

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