FORMULARY MANAGER v ASTRAZENECA

Conduct of representative

A formulary manager at a hospital NHS Trust, complained about the conduct of a representative from AstraZeneca in relation to the promotion of Crestor (rosuvastatin).

Crestor had been turned down by the drug and therapeutics committee (D&TC) in February 2007. The representative had not come to the pharmacy to find out the decision but proceeded to discuss the benefits of the product with several key consultants.

In August when the representative contacted the complainant to find out the decision, the representative queried it and continued to argue the merits of the product. The sensitivity required and respect for the local decision of the trust was neither appreciated nor adhered to. For these reasons the representative was asked not to visit the trust and to contact the chief pharmacist of the primary care trust (PCT) if the representative wished to discuss Crestor with local GPs.

The Panel noted from AstraZeneca that the representative had tried to make an appointment with pharmacy to discuss the outcome of the D&TC decision but was turned away at the reception desk. The Panel noted that the PCT did not have a formal policy for seeing representatives. The representative appeared to have been told by the chief cardiologist in February that Crestor was on the formulary and in May that that was no longer so. The representative continued to promote Crestor to consultants conveying the formulary status. In August the representative and the complainant had met to discuss why the Crestor application had been rejected.

The Panel noted that the complainant had not commented upon or provided a copy of the email stating that Crestor was on the formulary which AstraZeneca submitted had been sent by the complainant to the chief cardiologist

The Panel noted that there was no formal policy regarding the conduct of representatives at the trust. It was not necessarily a breach of the Code to promote a product that was not on the formulary.

The Panel noted that the parties' accounts were different but not inconsistent. It was not unreasonable for a representative to query a decision and discuss the merits of that decision. Whilst so doing, the Code required representatives to maintain a high standard of ethical conduct. The Panel was concerned about AstraZeneca's submission that the representative accepted that she was, *inter alia*, facetious during her conversation with the complainant. However this was not specifically mentioned by the complainant.

The Panel considered that with regard to the representative discussing the D&TC decision there was some confusion. There was insufficient evidence to show that on the balance of probabilities the representative had not visited the pharmacy to find out the decision as alleged by the complainant.

The Panel considered that given all the circumstances there was no breach of the Code and thus ruled accordingly.

A formulary manager at a hospital NHS Trust complained about the conduct of a representative from AstraZeneca in relation to the promotion of Crestor (rosuvastatin).

COMPLAINT

The complainant stated that Crestor had been turned down by her drug and therapeutics committee (D&TC) in February 2007. The representative had not come to the pharmacy to find out the decision but proceeded to discuss the benefits of the product with several key consultants. The representative circulated views between consultants and continued to promote the product's perceived benefits.

When finally in August the representative contacted the complainant to find out the decision, the representative queried it and continued to argue the merits of the product. The sensitivity required and respect for the local decision of the trust was neither appreciated nor adhered to. For these reasons the representative was asked not to visit the trust and to contact the chief pharmacist of the local primary care trust (PCT) if the representative wished to discuss Crestor with local GPs.

When writing to AstraZeneca to inform it of the complaint, the Authority asked it to respond to the requirements of Clauses 15.2 and 15.4 of the Code.

RESPONSE

AstraZeneca submitted that it took all allegations of inappropriate conduct very seriously and as soon as the complainant contacted it directly in August, it started an immediate investigation. Pending the outcome of this, the representative was informed by her line manager on the next day that she would not work in local PCTs or its hospitals until further notice. AstraZeneca telephoned the complainant twice in August and had a lengthy discussion about what had transpired, her concerns, corrective actions and future communications.

The representative in question had been with the company since 2001 and had passed her ABPI examination.

The representative's last training course was in 2007 and she was validated by internal and external assessors (a PCT prescribing lead). The details were provided. Her performance ratings for the past 2 years had been excellent. In addition, in July 2007 she signed off 14 corporate governance policies including the ABPI Code – for 10 of the policies (including the Code) achieving a 100% pass rate on her first attempt. A previous manager described the representative as 'an excellent rep' with 'good rapport' with her customers. Her key strengths being her ability to challenge and her clinical data knowledge – both of which lent themselves to confidence in front of customers. One of the representative's customers, (a cardiologist) stated that 'her professional conduct is exemplary'.

The D&TC met in February 2007 and considered the inclusion of Crestor onto the formulary. A thorough literature review was conducted, lots of debate ensued and the decision to reject the application was not made lightly. Although the complainant stated that all representatives were briefed by pharmacy to contact it with regards to D&TC decisions, the representative had tried on many occasions to see the complainant to determine what decision had been reached and how, but she was turned away at the pharmacy reception desk. It was evident that pharmacy had not communicated any policy to her on when the complainant saw representatives. This concurred with the complainant's statement that the representative never saw her after the D&TC's decision was made and no hospital policy was available for any representative to see (and therefore adhere to).

The representative stated that a chief cardiologist told her in February that Crestor was on the formulary and she wanted to see pharmacy to see when and how it would issue guidance to the hospital but was unable to see the complainant. Although the chief cardiologist was unavailable for interview as he was currently on annual leave, his colleague, a cardiologist, corroborated this statement because on more than one occasion he was a witness when the chief cardiologist verbally told the representative that Crestor was on the formulary.

According to the representative, a few months before May the complainant had emailed the chief cardiologist, stating Crestor was on the formulary and she saw this email. AstraZeneca was unable to trace this email as the chief cardiologist was at present on annual leave. The representative believed that the decision was then overturned by the complainant. The cardiologist recalled that there was some confusion with clinicians as to the formulary status of Crestor and noted that at one new medicines committee meeting, the chief cardiologist said he thought Crestor was on the formulary and was surprised that it wasn't. The cardiologist stated 'poor [the representative] is an innocent victim of miscommunication'.

AstraZeneca submitted that in May the chief cardiologist told the representative that Crestor was not on the formulary. She continued to promote the product to consultants, conveying to them the formulary status, talked to them about where they used it, discussed referrals, the opinion of the PCT and what needed to be done to get it accepted onto the formulary next time. Although the complainant considered that the representative should not have promoted Crestor at all, in the absence of any such hospital policy directing this, the representative continued to do her job.

AstraZeneca submitted that in August, the representative met the complainant to discuss why the Crestor application had been rejected. When the representative mentioned the email from the complainant to the chief cardiologist, she immediately recognised that the complainant thought she was rude and not understanding but she alleged that she was 'privy to information she (the complainant) didn't want me to have, no one likes to be proved wrong'. The representative accepted that she was challenging and facetious during their conversation.

In conclusion from internal investigations it was apparent that the representative respected and understood the D&TC and its decisions and did not promote Crestor as being on formulary as soon as she knew of this change and accepted that she was facetious in August during a conversation with the complainant. Further discussions with the representative would establish next steps, in terms of her behaviour going forwards and her role within the NHS trust.

AstraZeneca submitted that the corporate compliance leader had apologised unreservedly to the complainant on behalf of the representative, for any inappropriate behaviour or conduct, or if any offence was taken. In addition, she had reassured the complainant that AstraZeneca would write to the chief pharmacist and the complainant and agree to abide by the local arrangements in place with respect to the representative and the promotion of Crestor.

AstraZeneca submitted that with respect to the allegation of misconduct, it was extremely disappointed that a member of the hospital trust felt compelled to complain to the PMCPA. The company was confident that the representative had maintained a high standard of ethical conduct in the discharge of her duties and, on this occasion, as the conversation was between two parties with no witnesses, it was difficult for anyone else to judge what occurred and draw an absolute conclusion. Nevertheless AstraZeneca apologised unreservedly if any offence was taken but did not accept that it was in breach of Clause 15.2.

With respect to Clause 15.4, all parties accepted that there were no local arrangements in place and therefore AstraZeneca submitted that it was not in breach of this clause.

Further comments from the complainant
The complainant was asked to comment on AstraZeneca's response before the Panel made its ruling.

The complainant stated that to her knowledge, no attempt was made to make an appointment with pharmacy to ascertain the trust decision regarding Crestor. Time was allocated to ensure that communications were clear and unambiguous and to facilitate adherence to trust decisions by representatives. There were no records that appointments were made by the representative.

Although the trust did not have a formal policy for representatives at present, good practice of representatives and the availability of pharmacy to meet with representatives to confirm formulary status avoided unacceptable promotion of non formulary medicines.

The complainant noted the statement 'On [May] the representative was informed … that Crestor was not on the formulary. She continued to promote the product to consultants …'. This contradicted the statement in the conclusion '[the representative] …stopped promoting Crestor as being on formulary as soon as she was made aware of this change …'.

PANEL RULING

The Panel noted from AstraZeneca that the representative had tried to make an appointment with pharmacy to discuss the outcome of the D&TC decision but was turned away at the reception desk. The Panel noted that the trust did not have a formal policy for seeing representatives. The representative appeared to have been told by the chief cardiologist in February that Crestor was on the formulary and in May that that was no longer so. The representative continued to promote Crestor to consultants conveying the formulary status. In August the representative and the complainant had met to discuss why the Crestor application had been rejected.

The Panel noted that the complainant had not commented upon or provided a copy of the email stating that Crestor was on the formulary. AstraZeneca submitted that this had been sent by the complainant to the chief cardiologist.

The Panel noted that there was no formal policy regarding the conduct of representatives at the trust. It was not necessarily a breach of the Code to promote a product that was not on the formulary.

The Panel considered that AstraZeneca's response was not contradictory as suggested by the complainant. The representative had not stopped promoting Crestor but had stopped promoting it as being on the formulary.

The Panel noted that the parties' accounts were different but not inconsistent. It was not unreasonable for a representative to query a decision and discuss the merits of that decision. Whilst so doing, the Code required representatives to maintain a high standard of ethical conduct. The Panel was concerned about AstraZeneca's submission that the representative accepted that she was, *inter alia*, facetious during her conversation with the complainant. However this was not specifically mentioned by the complainant.

The Panel considered that with regard to the representative discussing the D&TC decision there was some confusion. There was insufficient evidence to show that on the balance of probabilities the representative had not visited the pharmacy to find out the decision as alleged by the complainant.

The Panel considered that given all the circumstances there was no breach Clauses 15.2 and 15.4 of the Code.

Complaint received	**2 August 2007**
Case completed	**24 October 2007**