CASE AUTH/2922/12/16

ASSISTANT DIRECTOR MEDICINES MANAGEMENT v MEDA

Conduct of representative

An assistant director, medicines management, complained about the activities of a representative from Meda Pharmaceuticals at a GP meeting. The complainant stated that the representative distributed leaflets about Dymista (fluticasone/azelastine for perennial and seasonal allergic rhinitis) and stated that local consultants recommended the product. However, the local area prescribing committee had reviewed the product and recommended that it should be grey listed and thus not be prescribed by either primary care or secondary care (not on any hospital formulary in the area). The complainant pointed out the grey recommendation to the representative and how he/she was promoting against the local NHS guidance.

The complainant stated that from there the representative became very combative and arrogant. He/she shouted the complainant down and stated in front of the audience of GPs and practice managers that it was just guidance and GPs could prescribe anything they wished. The representative then stated that he/she would put the complainant in touch with the formulary pharmacist of the local area trust who would, in his/her words, 'set you right'. The complainant stated that she had known the local formulary pharmacist and on speaking to him after this event, he was particularly disturbed that his name was brought up by the representative when they had had no contact in over two years.

The detailed response from Meda is given below.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. The complainant had consistently alleged that the representative had not proactively referred to the local formulary status of Dymista. The complainant had also consistently described the representative's conduct as combative even if that was not the representative's view of his/her behaviour. A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel noted that the issue which had led to the disagreement between the parties centred around the status of Dymista on the local prescribing formulary. In March 2014 the local area prescribing committee had deemed Dymista as a 'grey' product ie it was not recommended for use. It appeared that this decision had been appealed and committee minutes from October 2014 stated that the Dymista appeal had helped to clarify the appeals process and that any appeal must be process-driven and that the committee could make recommendations but the individual prescriber made the clinical decision on whether or not to prescribe. It thus appeared to the Panel that in October 2014, although Dymista was still grey listed the committee's recommendation not to use it was just that – a recommendation, not a mandate. Nonetheless, the Panel noted that the representative in question clearly knew that history of Dymista locally but chose not to proactively inform the audience of its status. The representative stated that he/she did not clarify the Dymista formulary status before he/she detailed the product. In the Panel's view, to detail a product without reference to its local prescribing status at the outset was unhelpful and misleading. The Panel ruled a breach of the Code. Whilst the Panel did not know exactly what the representative had stated regarding the local prescribing of Dymista, it considered that on the balance of probabilities he/she created an impression which could not be substantiated. On balance, the Panel ruled a breach of the Code. In the Panel's view, the representative had not maintained a high standard of ethical conduct and a breach of the Code was ruled.

The Panel did not consider that the complainant had demonstrated that, on the balance of probabilities, the representative was combative and so in that regard it ruled no breach of the Code.

The Panel noted its rulings above and although it was concerned that the representative had not proactively referred to the local formulary status of Dymista, it nonetheless did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

An assistant director, medicines management complained about the activities of a representative from Meda Pharmaceuticals Limited at a GP meeting held in December 2016. The representative provided sandwiches and was given ten minutes at the start of the evening to talk about Meda's products.

COMPLAINT

The complainant stated that the representative distributed leaflets about Dymista (fluticasone/azelastine for perennial and seasonal allergic rhinitis) and stated that local consultants recommended this product. However, the local area prescribing committee had reviewed this product and recommended that it should be grey listed and thus not be prescribed by either primary care or secondary care (not on any hospital formulary in the local area). The complainant pointed out the grey recommendation to the representative and how GPs and local consultants were recommended not to

prescribe Dymista and that he/she was promoting against the local NHS guidance.

The complainant stated that from there the representative became very combative and arrogant. He/she shouted the complainant down and stated in front of the audience of GPs and practice managers that it was just guidance and GPs could prescribe anything they wished. The representative then stated that he/she would put the complainant in touch with the formulary pharmacist of the local area trust, who would, in his/her words, 'set you right'. The complainant stated that she had known the local formulary pharmacist for many years and on speaking to him after this event, he confirmed that he had not spoken to the representative in over two years and he also found him/her combative and ignorant. The local formulary pharmacist was also particularly disturbed that his name was brought up by the representative when they had had no contact in over two years.

The complainant was concerned about the combative and ignorant attitude of the representative and the fact that Meda had actively promoted a product against the local guidance, and if questioned, then asked GPs to ignore that guidance.

In writing to Meda, the Authority asked it to respond in relation to the requirements of Clauses 2, 7.2, 7.4, 9.1 and 15.2.

RESPONSE

Meda stated that it did not believe that it had breached Clause 2. The representative in question was interviewed and he/she detailed the sequence of events and considered that he/she had acted properly and in accordance with the expected behaviour of a Meda representative and of the pharmaceutical industry on the whole, in line with the Code.

Meda submitted that it was legitimate for the industry to highlight available clinical evidence, both randomised clinical trials and real life and local and national specialist clinical consensus and practice (the British Society for Allergy and Clinical Immunology (BSACI) conference/local trust). It was necessary to discuss identifiable NHS system inefficiencies (specialist outpatient prescriptions being challenged following referral when appropriately prescribed within licence based on specialist clinical assessment and history). It was essential that there was an open environment to have this discussion, especially, when local prescribing guidance was different to other large and highly regarded health economies.

The repeated applications from leading national specialist consultants in the local area trust with real-life clinical experience was highly relevant. As was the clinical usage of Dymista locally – it highlighted reasonable clinical usage above IPR level and aligned to research suggested unmet need with conventional standards of care and position for Dymista in sequential pathways as a step-up option.

Meda referred to the interview transcript whereby the representative confirmed that the local formulary pharmacist was mentioned but disagreed that the words 'set you right' were used. The representative clarified that he/she had referred to the local formulary pharmacist only to highlight that he had supported another customer applying for formulary application for Dymista. Meda had also been able to verify email correspondence between the local formulary pharmacist and that customer.

Meda stated it had no reason to doubt the representative's account and concluded that there had been a misunderstanding between the representative and the complainant. The representative did not intend to contradict the complainant, but to direct her to differences of opinion relating to the guidelines.

Meda submitted that it had not breached Clauses 7.2 and 7.4; the complainant had not objected to promotional materials. The Dymista leavepiece was provided which had been produced in line with requirements of the Code and approved following internal Meda processes.

Meda submitted that there was no breach of Clause 9.1. All Meda representatives were regularly trained and the representative in question was fully aware of the importance of maintaining high standards. He/she had been in the industry for a long time, and had not been previously involved in any complaints from health professionals in relation to his/her conduct and behaviour in his/her time with Meda.

Meda submitted that there was no breach of Clause 15.2. Like all Meda representatives, the representative in question had been trained on the Code on an annual basis. He/she had been trained and examined on the promoted medicines to ensure that he/she was able to provide full and accurate information. He/she was aware that Meda representatives must at all times maintain ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.

Furthermore, Meda had an in-house voluntary e-training system, which sent daily random questions on the Code and promoted products, to reinforce the employees' knowledge. Meda invested time and resources on employee education and training.

Whilst Meda noted that this was the first complaint against the representative, he/she was reminded during the interviews of the high standards expected for interactions with customers and of Meda's obligations under the Code and would be retrained in that regard.

Meda would welcome an opportunity to reach out to the complainant in order to establish a dialogue if that would be beneficial. The company took the views of health professionals seriously.

From the interview transcripts, the representative stated that there was a ten minute presentation on three products. The leavepieces for Dymista, Elleste (oestradiol) and Treclin (clindamycin/tretanoin) were left on the seats. The representative used his/her iPad to present the Dymista and Treclin e-details.

According to the representative, some said that Dymista was grey listed and not to be prescribed but some used it according to prescribing committee minutes. Some clinical commissioning groups (CCGs) were happy to prescribe Dymista and others, especially the complainant's CCG, were not. According to the representative, the complainant's CCG followed the prescribing committee minutes which stated not to prescribe in primary and secondary care. According to the representative, he/she noted that there was an update in October which the complainant was reluctant to accept but checked her laptop and read out the update. The complainant then suggested another formulary application was submitted. The representative said that the consultant had applied and the local area formulary pharmacist was very supportive to this customer.

The representative denied there was any sort of an argument.

When asked by the Panel if it could send its response to the complainant for comment, given that the parties' accounts were so different, Meda stated that it had tried to contact those who had attended the meeting but that those who were contactable were unwilling to provide an account of the events.

FURTHER COMMENTS FROM THE COMPLAINANT

The complainant noted Meda's submission that it had carried out a thorough investigation and tried to contact those who were at the meeting but unfortunately those contactable were unwilling to provide an official account of the event. As far as the complainant knew, the only person Meda had contacted was one of the practice managers at the meeting; that person was also mentioned in the interview transcript.

The complainant had spoken to the practice manager and she was willing to provide an official account of the event; contact details were provided.

The complainant queried who from the attendance list of the meeting Meda had tried to contact that were unwilling to provide accounts of the event as they also might be happier to provide an account to the PMCPA rather than to Meda.

The complainant noted Meda's submission that she had taken the view that Dymista had been grey listed. The complainant noted that as previously pointed out to the representative it was not just her view, this was the current position of the area prescribing committee. The complainant provided a link to the published guidance. The complainant noted that the recommendations on the local area prescribing committee website were kept up-to-date and if this recommendation had been withdrawn it would be stated so in both the title and the link.

The complainant submitted that the current Dymista recommendation had been published on the website since March 2014 when this was decided. The complainant noted that in January 2017 there was a further application to change the status of this recommendation and so this recommendation would be updated once agreed by the area prescribing committee.

The complainant noted Meda's submission that it was 'legitimate for the industry to highlight available clinical evidence, both randomised clinical trials and real life, local and national specialist clinical consensus' and that 'it was essential that there was an open environment to have this discussion especially when local prescribing guidance was different to other large and highly regarded health economies'. However in this case the Meda representative did not highlight all available information to those at the meeting in question; he/she chose to knowingly not mention the grey listing published on the website of the local area prescribing committee when he/she promoted Dymista to the clinicians present. The complainant stated that once she pointed out that piece of information the representative became aggressive and combative.

The complainant noted that Meda had stated that she had taken the view that there could be no discussion or promotion of Dymista. The minutes of the interview mentioned a meeting that she had had last year with the representative and one of his/her colleagues. The complainant confirmed that she and a colleague met with the two Meda employees. At that meeting they noted the grey status of Dymista locally and that they did not want to go through any clinical trial data until the status had been changed. At that meeting the representative knew about the grey status of Dymista and did not point out at that stage that he/she had used the minutes of the area prescribing committee meeting rather than the official published recommendation to promote Dymista. If he/she had, they could have clarified the situation at that point. The representative also did not ask for a written letter from the CCG asking him/her not to promote, the complainant would have thought a publicly available grey listing would have been sufficient to be aware of the CCG's position on the medicine, which she considered it was from the comment in the transcript 'Some CCGs are happy to prescribe and some aren't especially [the complainant's] CCG'.

The complainant stated that at the meeting in December, the representative mentioned where he/she had taken a few of the local GPs out to dinner to discuss Dymista and that they had thought it acceptable to prescribe Dymista. The complainant submitted however, that a decision at a meal sponsored by Meda with local GPs did not constitute a CCG decision that its GPs prescribe. Any decision would need to follow local procedures. At this point one of the GPs who was at the meal joined the meeting and gave a different recollection of the evening meal meeting and stated that he was aware of the grey status of Dymista.

The complainant noted that in an interview transcript the representative stated 'I would never do this to anyone else'. On reading that it made the complainant feel as if the representative knew that he/she had not treated her with respect at the meeting.

On the last page of the transcript when asked did anyone else at the meeting get involved, the representative stated 'No'. The complainant stated that this was incorrect because the chair of a local medicines management committee commented that he knew about the grey status of Dymista.

The complainant noted that at various points in the transcript it mentioned an argument. The complainant agreed there was no argument, just a differing of opinion; she would not let the situation become an argument in an open meeting. It was the combative and arrogant attitude of the representative that was inappropriate.

The complainant agreed that she did not object to the promotional materials; her only concern was the representative's inappropriate behaviour. The complainant considered that the interview transcript showed the representative's arrogance to accept when he/she was wrong, even when she pointed out the official grey status publication, and it looked like the representative was still unwilling to accept he/she was wrong.

FURTHER COMMENTS FROM MEDA

Meda stated that it would very much appreciate the recollection of accounts by other meeting attendees, given the only accounts of the events that were available thus far were from the complainant and the representative. Meda asked that the additional accounts be made available for review.

Meda stated that in a third interview with the representative, the complainant's comments that he/she had knowingly chosen not to mention the grey listing for Dymista when promoting to the clinicians in the room was highlighted. The representative agreed that he did not actively raise this but when this was highlighted, he/she acknowledged and respectfully agreed with the Dymista grey listing.

Meda stated that the representative was mortified to read that he/she had shown disrespect to the complainant. He/she stated unequivocally that he/she would never knowingly show a lack of respect or speak out of turn with any health professional. He/she asked to note his/her sincere and humble apology for having given the complainant the impression that he/she was not being respectful.

The representative confirmed that the chair of the local medicines management committee entered the meeting room, however he/she did not recall talking with him; it was possible that the chair, as part of the round table discussion, might have mentioned the grey listing status, but if that was the case he/she did not hear the comment.

Meda also agreed that there was no argument. Due to 'cultural differences' (English was the representative's second language), and personalities between the complainant and the representative, there could potentially have been a disconnect and misunderstanding. For this the representative was profoundly apologetic for showing any unintended disrespect towards the complainant.

Meda reiterated that all representatives conducted themselves in line with Code expectations. In addition, Meda provided emotional intelligence awareness training to ensure that the representatives understood the need to engage with their clients on an individual basis and flex their personality styles accordingly.

Meda renewed its offer to engage with the complainant and for the representative to personally apologise for the misunderstanding.

Following the additional interview, Meda still considered that the representative did not breach the Code, however, as stated above, he/she apologised for any perceived disrespect or offence caused.

PANEL RULING

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. The complainant had consistently alleged that the representative had not proactively referred to the local formulary status of Dymista. The complainant had also consistently described the representative's conduct as combative even if that was not the representative's view of his/her behaviour. A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel noted that the issue which had led to the disagreement between the parties centred around the status of Dymista on the local prescribing formulary. In early 2014 the local area prescribing committee had deemed Dymista as a 'grey' product ie it was not recommended for use. It appeared that this decision had been appealed and committee minutes from later in 2014 stated that the Dymista appeal had helped to clarify the appeals process and confirmed that any appeal must be process-driven and that the committee could make recommendations but the individual prescriber made the clinical decision on whether or not to prescribe. It thus appeared to the Panel that in October 2014, although Dymista was still grey listed the committee's recommendation not to use it was just that – a recommendation, not a mandate. Nonetheless, the Panel noted that the representative in question clearly knew that history of Dymista locally but chose not to proactively inform the audience of its status. The representative stated that he/she did not clarify the Dymista formulary status before he/she detailed the product. In the Panel's view, to detail a product without reference to its local prescribing status at the outset was unhelpful and misleading. The Panel ruled a breach of Clause 7.2. Whilst the Panel did not know exactly what the representative had stated regarding the local prescribing of Dymista, it considered that on the balance of probabilities he/she created an impression which could not be substantiated. On balance, the Panel ruled a breach of Clause 7.4. In the Panel's view, to mislead a local audience in that regard

meant that the representative had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled. The Panel considered that this ruling covered any consideration of the requirements of Clause 9.1 and so it made no additional ruling in that regard.

The Panel did not consider that the complainant had demonstrated that, on the balance of probabilities, the representative was combative and so in that regard it ruled no breach of Clause 15.2.

The Panel noted its rulings above and although it was concerned that the representative had not proactively referred to the local formulary status of Dymista, it nonetheless did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

Complaint received **19 December 2016**

Case completed **24 March 2017**
