CLINICAL LEAD PHARMACIST v PROSTRAKAN

Conduct of representatives

A clinical lead pharmacist at a hospital NHS foundation trust, complained about the conduct of ProStrakan representatives in relation to the promotion of Abstral (fentanyl) which was indicated for the management of breakthrough pain in adults using opioid therapy for chronic cancer pain.

The complainant referred to a meeting in the urology department to discuss using Abstral in oncology patients presenting with cancers of urological origin. This was within licence as the complainant understood it. However, the discussion moved to the use of Abstral post-operatively in patients who had had urological surgery. This was outside licence although technically these patients would have had surgery for an oncological reason. The complainant was not clear who initiated this discussion but the representative did not try to extract herself from the discussion on the basis that it was an unlicensed indication and it should not be discussed.

The upshot of the meeting was that one of the attendees, a specialist nurse, contacted the acute pain team to discuss using Abstral in this way. The complainant confirmed with ProStrakan that it had no data to support this indication.

At this point the complainant became aware of the meeting. Since then he had had a meeting with the representative and her line manager. They initially contested his view of the licence and whether their product was licensed but they also apologised. However the complainant considered that a more formal acknowledgement and possible rebuke of their activities might be in order.

The detailed response from ProStrakan is given below.

The Panel noted that the issue was in relation to using Abstral post-operatively following urological surgery. In the complainant's view this was outside the licence. ProStrakan submitted that its representative had discussed the use of Abstral in patients with urological cancers undergoing surgery purely on the basis that such patients might still be subject to breakthrough pain post-operatively despite receiving other opioid treatment for chronic cancer pain. Urological surgery might be focussed on debulking tumours and/or relieving urological obstruction. In such cases the patient would still be a cancer sufferer. ProStrakan agreed with the complainant that if surgery removed the cancer the patient would not have breakthrough cancer pain.

The Panel considered that it was important that representatives were very clear about the indications for use of the products they promoted. It would be unacceptable to promote Abstral in patients who did not have cancer however there was no evidence that this had happened. The Panel considered that the complainant had not proven his case on the balance of probabilities and no breach of the Code was ruled. Consequently the Panel did not consider that the representative had failed to maintain a high standard of ethical conduct or failed to comply with the Code. No breach of the Code was ruled.

The representative's presentation included an introduction to breakthrough cancer pain. The Panel noted that the presentation did not give the full indication. The brand logo referred to breakthrough cancer pain but there was no mention that patients needed to be using opioid therapy for chronic cancer pain. The Panel considered that this would have been helpful but the absence in the particular circumstances of this case did not amount to a breach of the Code.

The Panel did not consider that the briefing material advocated a course of action likely to breach the Code and thus no breach of the Code was ruled.

Given its rulings above the Panel decided that there was no breach of Clause 2 and ruled accordingly.

A clinical lead pharmacist at a hospital NHS foundation trust, complained about the conduct of representatives of ProStrakan Ltd in relation to the promotion of Abstral (fentanyl). Abstral was indicated for the management of breakthrough pain in adults using opioid therapy for chronic cancer pain.

COMPLAINT

The complainant referred to an organised meeting within the urology department in late June to discuss using Abstral in oncology patients presenting with cancers of urological origin. This was within licence as the complainant understood it.

The meeting then began to discuss using Abstral in the post-operative phase for patients having urological surgery. This was outside licence although technically these patients would have had surgery for an oncological reason. The complainant was not clear who initiated this discussion but the company representative did not try to extract herself from the discussion on the basis that it was an unlicensed indication and it should not be discussed.

The upshot of the meeting was that one of the specialist nurses at the meeting contacted the acute pain team to discuss using Abstral in this way. The complainant confirmed with ProStrakan that it had no data to support this indication.

At this point the complainant became aware of the meeting. Since then he had had a meeting with the

representative and her line manager. They initially contested the complainant's view of the licence and whether their product was licensed but they also apologised. However the complainant considered that a more formal acknowledgement and possible rebuke of their activities might be in order.

When writing to ProStrakan, the Authority asked it to respond in relation to Clauses 2, 3.2, 15.2 and 15.9 of the Code.

RESPONSE

ProStrakan submitted that it appeared that the crux of this case rested on the use of Abstral in patients with urological cancers who underwent surgery. The complainant had raised concerns that use of the product in such circumstances was off-label, and as such the discussion of this use by a representative constituted off-label promotion. ProStrakan also noted that the complainant appeared not to have attended the meeting where the alleged discussion took place, but was made aware of the meeting afterwards as a consequence of an individual contacting the acute pain team.

While ProStrakan fully respected the complainant's concerns, it noted that the use of Abstral in the patient group described above was discussed in the meeting by ProStrakan's representative purely on the basis that patients with urological cancers might still be subject to breakthrough cancer pain post-operatively despite receiving other opioid treatment for chronic cancer pain. While radical surgery might be curative for some patients, not everyone with urological cancer would be suitable for radical procedures or subject to a curative outcome; surgery might instead focus on debulking tumours and/or relieving urological obstruction. In such cases the patient would still have cancer and thus potentially be subject to episodes of breakthrough cancer pain. In such cases the use of Abstral to relieve this pain would be appropriate and within licence.

ProStrakan's records showed that one of its representatives held a meeting in the urology department of the hospital but that this meeting was held in early May, not in late June as stated by the complainant. The meeting (held in early May) was a urology department event which was held regularly to meet with industry representatives. At this meeting a second representative presented on both Abstral and Tostran (testosterone) 2% Gel. The presentation on Abstral was run from an iPad (Abstral App, ref M017/0580c). A hard copy of the item was provided. As the meeting was part of an ongoing series organised by the urology department no formal agenda was produced and no additional materials were provided to the attendees. The meeting was attended by urologists and associated multidisciplinary health professionals.

When questioned about the meeting the representative mentioned that some of the urologists discussed the post-operative use of Abstral. They were interested in the use of the product and requested a follow-up call to the surgical recovery nurse that supported their team.

The representative stipulated that, to the best of her recollection, discussion centred around the post-operative use of Abstral in patients with urological cancers, specifically the urologists were interested in the possible use of Abstral for breakthrough pain in cancer patients post-operatively, eg the use of Abstral for episodes of breakthrough pain that occurred when cancer patients started to mobilise again following a surgical procedure. The representative considered that this use was within licence as the product would still be used to treat breakthrough cancer pain in patients with urological cancers.

ProStrakan submitted that the follow-up call to the surgical recovery nurse was made in late May. This visit was supervised by the representative's manager who was on a field visit with her that day. During this call the use of Abstral was discussed, but these discussions were strictly held within the licensed indication as evidenced by the field visit report which specifically mentioned that the promotion was within licence and that the nurse in question was clear about the licensed indication. Promotion of Abstral within its licensed indication was very important to ProStrakan and the risk management plan for Abstral, and as such was evaluated and assessed regularly on field visits. A second visit was made to this nurse in late June, but again discussions were regarding the licensed indication of Abstral.

On the Friday following this meeting the representative's manager was contacted by the complainant to discuss the use of Abstral in the hospital. As a consequence, a meeting was arranged in July between the second representative, the complainant and the first representative. ProStrakan submitted that during this meeting the three participants discussed the promotion of Abstral and its licensed indication. As ProStrakan understood it, the complainant's view of post-operative use differed slightly from ProStrakan's, as he put forward the view that cancer patients who had undergone surgery to remove the cancer were no longer cancer patients, and thus not appropriate patients for treatment with Abstral.

ProStrakan agreed with the complainant on this point. A patient who had been cured of cancer was no longer subject to breakthrough cancer pain, and was thus ineligible to be treated with Abstral. However, as detailed above, this was not what was promoted by the ProStrakan representative during the postgraduate meeting in early May. Not every patient undergoing surgery for urological cancer would be cured, and as such some might still suffer breakthrough cancer pain. Given that this was the case, ProStrakan considered that use of the product in these patients, and promotion of Abstral to the health professionals that treated them, was both appropriate and within the Code.

ProStrakan made every effort to ensure that the promotion of its products was conducted in a compliant and ethical manner. Not only was the initial training that its representatives received very important, but it also ensured that this training continued during their time with ProStrakan. Field

visits, in which a representative was observed in situ by his/her manager, were common. These ensured that high standards were maintained in all aspects of an individual's working life. During her time with ProStrakan the first representative had regularly received field visits from her line manager. These visits had consistently demonstrated that she had a clear and accurate understanding of the licensed indication for Abstral.

While ProStrakan respected the complainant's view it believed that the promotion of Abstral by its representatives had at all times been within the licensed indication, and thus a breach of Clause 3.2 was not warranted.

Further to this, ProStrakan had found no evidence that either of its representatives acted in contravention of this indication and argued that Clause 15.2 had not been breached.

A copy of the training material (Abstral Training Manual, ref M017/0456) used to clarify the licensed indication for Abstral was provided. ProStrakan submitted that the document to instruct its representatives on the way in which they should conduct themselves was sufficiently clear, and that it did not advocate a course of action that was likely to lead to a breach of the Code. There was no breach of Clause 15.9.

As a consequence ProStrakan also believed that a ruling of a breach of Clause 2 was not justified in this instance.

In response to a request for further information, ProStrakan stated that the meeting with the nurse in late June was not the meeting referred to by the complainant. However, without the ability to ask the complainant directly it was not possible to be certain.

ProStrakan agreed that a meeting was indeed scheduled with the urology department to discuss the use of Abstral. However, it believed that the complainant was mistaken about the date on which it occurred. ProStrakan's records showed that this meeting was held in early May. It was the only meeting held by the representative that fitted the complainant's description.

The meeting in late June was only attended by the representative, her manager and the nurse in question. No presentation was given. The meeting focused exclusively on the licensed indication as demonstrated by the field visit report. Field visit reports were provided for the meetings attended by the manager.

In response to a request for further information, ProStrakan noted that the meeting in the urology department in early May was attended by two urology consultants, two unnamed house officers and one other unnamed individual. The discussion was about the use and titration of Abstral (including its licensed indication) and patients that might be suitable for Abstral (including post-operative use in patients with cancer suffering from breakthrough cancer pain). ProStrakan provided details of which pages of the Abstral App were used by the representative in a presentation that lasted almost thirty minutes.

At the follow-up meeting in late May with the surgical recovery nurse no presentation was given and the discussion was about the use and titration of Abstral (stressing its licensed indication), end of life care, focusing on the treatment of breakthrough cancer pain and the potential advantages of Abstral to patients (specifically to those with renal impairment or who wished to be at home).

At a second meeting with the surgical recovery nurse in late June, again no presentation was given, and this time the discussion was on the use and titration of Abstral (including its licensed indication), quality of life for palliative care patients and the role that Abstral could play in improving quality of life for patients with breakthrough cancer pain.

ProStrakan noted that the complainant did not attend any of the meetings mentioned above, and thus was not present when the alleged off-licence discussion occurred.

ProStrakan reiterated that post-operative use of Abstral did not necessarily constitute off-label promotion. The representative in question stated that to the best of her recollection, discussion centred around the post-operative use of the product in patients with urological cancers, specifically stating that the urologists were interested in the possible use of Abstral for breakthrough pain in cancer patients post-operatively, eg the use of Abstral for episodes of breakthrough pain that occurred when cancer patients started to mobilise again following a surgical procedure. She stipulated that she considered that this use was within licence, as the product would still be used to treat breakthrough cancer pain in patients with urological cancers.

The presentation on Abstral was exclusively focused on use of the product within its licensed indication. According to the representative, participation in the discussion following the presentation had been limited, but that her understanding was that post-operative use in cancer patients suffering from breakthrough cancer pain was in licence.

PANEL RULING

The Panel noted that the complainant had not responded to the Panel's request for comments on the company's responses. It was often useful for the Panel to have comments on the response in cases like this where there appeared to be a difference of opinion. It was for the complainant to prove his/her complaint on the balance of probabilities. There appeared to be a difference of opinion as to when the meeting had taken place. The complainant referred to a meeting in late June and ProStrakan referred to a meeting in early May with the hospital urology department and follow up meetings with the surgical recovery nurse in late May and late June.

The Panel noted that the issue was in relation to using Abstral post-operatively following urological surgery. In the complainant's view this was outside the licence. ProStrakan submitted that its representative had discussed the use of Abstral in patients with urological cancers undergoing surgery purely on the basis that such patients might still be subject to breakthrough pain post-operatively despite receiving other opioid treatment for chronic cancer pain. Urological surgery might be focussed on debulking tumours and/or relieving urological obstruction. In such cases the patient would still be a cancer sufferer. ProStrakan agreed with the complainant that if surgery removed the cancer the patient would not have breakthrough cancer pain.

The Panel considered that it was important that representatives were very clear about the indications for use of the products they promoted. It would be unacceptable to promote Abstral in patients who did not have cancer however there was no evidence that this had happened. The Panel considered that the complainant had not proven his case on the balance of probabilities and no breach of Clause 3.2 was ruled. Consequently the Panel did not consider that the representative had failed to maintain a high standard of ethical conduct or failed to comply with the Code. No breach of Clause 15.2 was ruled.

The representative had presented from the Abstral App including an introduction to breakthrough cancer pain. The Panel noted that the presentation did not give the full indication. The brand logo referred to breakthrough cancer pain but there was no mention that patients needed to be using opioid therapy for chronic cancer pain. The Panel considered that this would have been helpful but the absence in the particular circumstances of this case did not amount to a breach of the Code.

The Panel did not consider that the briefing material advocated a course of action likely to breach the Code and thus no breach of Clause 15.9 was ruled.

Given its rulings above the Panel decided that there was no breach of Clause 2 and ruled accordingly.

Complaint received **16 July 2012**

Case completed **5 October 2012**