

GENERAL PRACTITIONER v NAPP

Conduct of representative

A general practitioner complained about the promotion of BuTrans (buprenorphine transdermal patches) by a Napp representative. The duty manager of an old people's home had asked the complainant to prescribe the product. It transpired that the representative had visited the home to promote a prescription only medicine; she had also left promotional leaflets and her business card with the duty manager.

The Panel noted that the establishment visited by the representative was staffed by social workers; such employees could be considered appropriate administrative staff, or as they administered medicines, they might even come within the definition in the Code of a health professional. They were not members of the public in that regard and thus the Panel ruled no breach of the Code. However these staff were not legally entitled to choose which medicine was prescribed; they administered medicines on behalf of the prescriber. In that regard the Panel considered that the information directed at such people would be different to that used with prescribers. The Panel did not consider that the leavepiece used with the staff at the home had been tailored to their needs; Napp had submitted that it was intended for GPs and nurses. The leavepiece was not tailored to the needs of non-medical staff who only administered medicines. BuTrans was a low dose, strong opioid preparation which should only be prescribed once a patient's previous opioid history and their current general condition and medical status had been considered. An anti-emetic was recommended for the first 7 days of BuTrans patch use. The Panel queried whether the staff at the home would have sufficient clinical knowledge to understand the implications of recommending BuTrans. The Panel considered that the representative had used a piece of promotional material with an audience for whom it had not been intended. High standards had not been maintained. Breaches of the Code were ruled.

The Panel did not consider that the home was a patient organisation ie advocacy group, as referred to in the Code and no breach of the Code was ruled.

Although very concerned about the promotion of a prescription only medicine to non-medical staff in this case, the Panel, on balance, considered that Napp's actions were not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. The final decision about what, if anything, to prescribe would always lie with the prescriber. No breach of Clause 2 was ruled.

A general practitioner complained about the promotion of BuTrans (buprenorphine transdermal patches) by a

representative of Napp Pharmaceuticals Limited.

COMPLAINT

The complainant stated that the duty manager old people's home in Scotland, recently asked her to prescribe BuTrans (buprenorphine) transdermal patches for some of its patients. It transpired that the representative in question had visited the home three or four times to promote a prescription only medicine; she had also left promotional leaflets and her business card with the duty manager.

The complainant alleged a breach of Clause 20.1 of the Code which stated that prescription only medicines must not be advertised to the public and Clause 20.3 which stated that information must be presented in a factual and balanced way and must not be designed to encourage patients to ask their health professional to prescribe a specific medicine.

BuTrans transdermal patches were not on the local formulary and were also not recommended by the Scottish Medicines Consortium (SMC).

It might be that the representative was unaware that she was only permitted to promote her products to health professionals and NHS managers but the complainant would be grateful if the matter could be investigated to ensure that this did not become a recurring problem.

When writing to Napp, the Authority asked it to respond in relation to Clauses 2, 9.1 and 15.2 of the Code in addition to Clauses 20.1 and 20.3 as cited by the complainant.

RESPONSE

Napp explained that the representative had visited the nursing home five times since February 2007 but had not seen the same health professionals each time. Two of these visits were solicited and three were unsolicited, but one of the unsolicited visits did not result in a completed call as no customers were available. She had no contact with the nursing home prior to February 2007.

The representative had arranged to meet the duty manager in February. However upon arrival she was told that the manager was unavailable and was asked to speak to a person whom she understood to be the Nurse in Charge. The representative gave a brief overview of BuTrans transdermal patches whereupon the Nurse in Charge thought that her staff would be interested in the product and asked the representative to return in May to give a presentation to a group of her staff.

When the representative duly arrived to give the presentation she was told that there had been an error with dates and staff availability and she was asked to return to meet nursing staff on later that month. Although she had a brief discussion about BuTrans patches with the duty manager and the Nurse in Charge the main presentation was deferred.

When, later in the month the representative presented information on BuTrans patches to a group of nurses at the home the meeting took place in a staff room out of earshot of patients, and the duty manager was not present. The representative demonstrated the use of a placebo patch and left some leavepieces (ref UK/BU-06081). The staff were very positive about the product and the representative was asked to follow up with the nursing home in the future.

In June, the representative called on the nursing home to see the Nurse in Charge who was unavailable. She left without discussing any products. In July the representative called again, but the Nurse in Charge was unavailable. A nurse who had not attended the meeting in May mentioned BuTrans patches and that he had heard about its potential benefits from his colleagues.

Napp emphasised that there had been no direct contact between the representative and any patient at this nursing home and her visits were conducted in a private room out of patients' earshot. Napp therefore assumed that the complainant was referring to discussions that took place with the duty manager.

Clause 1.1 clearly allowed medicines to be promoted to 'appropriate administrative staff' provided that all other provisions of the Code were met. Napp therefore maintained that it was entirely appropriate for the representative to give some very limited information about the product to the duty manager, so that he could make a judgment as to whether it would be appropriate to allow her to speak to his nursing staff. During the representatives' only brief discussion about BuTrans patches with the duty manager, in early May, the nursing home's Nurse in Charge was also present.

Clause 12.1 stated that promotional material should only be sent or distributed to those with a reasonable interest and that such material should be tailored to the audience. The leavepiece in question was intended for nurses and GPs and therefore the representative only left these with the nursing staff.

The complainant quoted the supplementary information to Clause 20 with reference to the fact that information should be presented in a factual and balanced way and not be designed to encourage patients to ask a health professional to prescribe a specific medicine. As far as Napp could tell from her letter, the complainant was contacted by the duty manager and not a patient. Thus there would appear to be no evidence at all that this provision had not been met.

On these grounds Napp strongly maintained that no breach of Clause 20 had occurred.

Napp acknowledged that BuTrans had not been approved by the SMC and was not on the local formulary. However the Code, and indeed UK legislation, did not restrict the rights of a pharmaceutical company to promote a product under such circumstances.

Napp continued to promote BuTrans in such circumstances in the belief that the rights of the health professional to decide what was best for the individual patient should be preserved.

Promoting a product that had been granted a marketing authorization by the Medicines and Healthcare products Regulatory Agency, but which had not been included on a particular formulary or recommended by the SMC, did not constitute a breach of the Code.

Napp believed that its representative had complied with the Code in all of her dealings with this nursing home. In particular she had conducted her discussions only with health professionals and appropriate administrative staff in suitably private locations. She had not exceeded allowable call rates and had used only certified materials which had been left with the intended and appropriate customers.

Napp therefore believed that she had maintained high standards of conduct in compliance with the requirements of Clauses 9.1 and 15.2, and furthermore that there were no grounds to suggest that Clause 2 had been breached.

In response to a request for further information Napp confirmed that the establishment visited by its representative was a care home for the elderly. Since the rules for promotion in care homes and nursing homes were identical as they related to the Code, Napp did not distinguish internally between them. The company used the terms synonymously.

Napp noted that the Code applied to 'health professionals and to appropriate administrative staff'. As defined in Clause 1.4 'health professional' included 'any other persons who in the course of their professional activities may prescribe, supply or administer a medicine'. Napp thus understood that staff working at a care home who administered medicines as part of their work were acting as health professionals rather than members of the public. The company submitted that the duty manager was appropriate administrative staff.

Care staff at the home did not wear uniforms.

Napp confirmed that its representative had asked the duty manager if she could speak to the Nurse in Charge and was directed to a named individual. At no time did the representative promote medicines to the patients (ie the public).

The Nurse in Charge was not a qualified nurse although at all times she was held out as the Nurse in Charge. At no time did she or anyone else state that she was not a qualified nurse. She had a social work

qualification and was the assistant manager of the home. As noted below, however, she was properly classed as a health professional.

Napp provided a list of the attendees to the meeting in May 2007; five were social care workers and three were social care assistants. The attendees were all selected by the Nurse in Charge as suitable and appropriate members of her staff to attend this meeting; the representative had no reason to believe otherwise.

Under the Medicines Act 1968 anyone, including social care workers and assistants in care homes could legally administer medicines to patients. Napp submitted that this qualified them as health professionals as defined by the Code.

The duty manager was not a qualified nurse but was a social worker by training. His duties and responsibilities within that role required him to have knowledge and awareness of the products being held at, administered and used at the home as well as their potential side effects. Napp submitted this qualified him as appropriate administrative staff as defined by the Code.

Napp submitted that its representative always intended to uphold high standards and that she had not promoted to the public as alleged.

PANEL RULING

The Panel noted that the Code applied to, *inter alia*, the promotion of medicines to members of the UK health professions and to appropriate administrative staff. The term 'health professional' included members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities might prescribe, supply or administer a medicine (Clause 1.4 referred).

The Panel was concerned that at the outset, Napp had not given a clear description of the establishment visited by the representative. Although the company submitted that the terms 'care home' and 'nursing home' were synonymous, in the Panel's view there was an important difference between the two – nursing homes would employ professionally qualified nurses whereas care homes would not necessarily do so. The Panel did not accept Napp's submission that the rules for promotion in care homes and nursing homes were identical as they related to the Code. The establishment visited by the representative was a care home and although it was staffed by social workers, Napp had initially referred to them as nursing staff and health professionals. This was not helpful. Napp's second response gave more information.

The Panel noted that the social workers at the care home could be considered appropriate administrative staff, or as they administered medicines they might even come within the definition in the Code of a health professional. They were not members of the public in that regard and thus the Panel ruled no breach of Clause 20.1. However these staff were not legally entitled to choose which medicine was prescribed; they administered medicines on behalf of the prescriber. In that regard the Panel considered that the information directed at such people would be different to that used with prescribers. The supplementary information to Clause 12.1 required promotional material to be tailored to the needs of the audience. The Panel did not consider that the leaflet used with the staff at the care home had been tailored to their needs; Napp had submitted that it was intended for GPs and nurses. The leaflet was not tailored to the needs of non-medical staff who only administered medicines. BuTrans was a low dose, strong opioid preparation for the treatment of severe opioid responsive pain conditions which did not adequately respond to non-opioid analgesics. The patient's previous opioid history and their current general condition and medical status should be considered. The leaflet stated that an anti-emetic was recommended for the first 7 days of BuTrans patch use. The Panel queried whether the staff at the care home would have sufficient knowledge about patients' previous medical history, current medical status or anti-emetic prescribing to be able to understand the clinical implications of recommending BuTrans. The Panel considered that the representative had used a piece of promotional material with an audience for whom it had not been intended. In that regard the Panel considered that high standards had not been maintained. Breaches of Clause 9.1 and 15.2 were ruled.

The Panel did not consider that the care home was a patient organisation ie advocacy group, as referred to in Clause 20.3 and cited by the complainant. No breach of that clause was ruled.

Although very concerned about the promotion of a prescription only medicine (CD (Sch3)) to non-medical staff in this case, the Panel, on balance, considered that Napp's actions were not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. The final decision about what, if anything, to prescribe would always lie with the prescriber. No breach of Clause 2 was ruled.

Complaint received	23 July 2007
Case completed	7 September 2007
