

# VOLUNTARY ADMISSION BY FERRING

## Representative-facilitated letter

Ferring Pharmaceuticals voluntarily admitted that one of its sales managers encouraged the representatives in his/her team to facilitate their local hospital to send a letter to local primary care practices encouraging the use of DesmoMelt (sublingual desmopressin) instead of Desmospray (desmopressin nasal spray). Ferring acknowledged that the sales manager's action, which was an entirely a local initiative, was inappropriate and constituted disguised promotion.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the Director treated the matter as a complaint.

The detailed response from Ferring is given below.

The Panel noted Ferring's submission that without its consent or approval, an area sales manager had drafted a letter for hospital consultants to send to local GPs recommending the use of DesmoMelt for primary nocturnal enuresis and discouraging the use of desmopressin nasal spray. The drafted text was, in effect, a piece of promotional material.

Regardless of the fact that no letters had been sent to GPs, the provision of the draft text, handwritten on a piece of notepaper, to the hospital consultants meant that they had been handed a piece of disguised promotional material and a breach of the Code was ruled.

The Panel considered that the creation of a piece of promotional material by an area sales manager, and its subsequent provision to health professionals, demonstrated an extremely poor understanding of the Code; it appeared that numerous clauses had not been complied with. The Panel considered that the representatives had not maintained a high standard of ethical conduct and breaches of the Code were ruled.

The Panel noted its rulings and comments above but considered that, on balance, and given the very limited reach of the material at issue (no letters were sent), the area sales manager's conduct was not such as to bring discredit upon, or reduce confidence in, the industry. No breach of Clause 2 was ruled.

Ferring Pharmaceuticals Ltd made a voluntary admission about the conduct of one of its representatives.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Ferring.

### VOLUNTARY ADMISSION

Ferring stated that a sales manager encouraged the

representatives in his/her team to facilitate their local hospital to send a product-related letter to local primary care practices. The letter was to be signed by the relevant hospital consultant and specifically encouraged GPs to use one particular formulation of a Ferring product instead of another. The activity was entirely a local initiative and came to the company's attention after an ex-employee raised concerns.

Ferring acknowledged that this activity was inappropriate and in breach of Clause 15.2. Because the letter was effectively disguised promotion, it also acknowledged that the activity was in breach of Clause 12.1.

Ferring was asked to provide the PMCPA with any further comments in relation to the requirements of Clauses 2, 9.1, 12.1 and 15.2.

### RESPONSE

Ferring submitted that it had a range of products to treat enuresis (bedwetting), including DesmoMelt, (sublingual desmopressin) for the treatment of primary nocturnal enuresis and Desmospray (desmopressin nasal spray), which was indicated, *inter alia*, for the treatment of nocturia.

Desmospray was previously indicated for primary nocturnal enuresis, but this indication was removed by the Medicines and Healthcare products Regulatory Agency (MHRA) in September 2007 due to concerns over safety in children. Ferring noted that there were generic versions of Desmospray available and whilst the Ferring sales team promoted DesmoMelt because of its more child-friendly delivery, both Desmospray and generic desmopressin sprays remained available because of their other indications.

In April 2016 a former representative emailed Ferring to raise concerns about the actions of his/her local area sales manager.

The area sales manager, who managed a small team and also had account responsibilities, had established a local initiative with the urology key account specialist. Ferring understood this had the combined objectives of communicating a genuine patient safety concern – hyponatremia in children was a serious adverse event – and boosting sales of DesmoMelt. The sales manager directed his/her representative to facilitate a letter from the local hospital to certain local GP practices. The letter was written by the area sales manager in draft (handwritten on note paper) and stated:

'Dear x

It has been brought to the attention of the XXXXX continence service that there is a disproportionate

amount of desmopressin spray/Desmospray being issued from your surgery. Please find attached information relating to the licence removal for the treatment of primary nocturnal enuresis and why we recommend the use of Desmomelt (desmopressin oral lyophilisate) instead.

We would be grateful if you would disseminate this information amongst the GPs in your surgery and make the appropriate changes.

[Signed relevant consultants in department].'

The representative was expected to ask the local enuresis team in the local hospital to send the text on hospital letterhead to local GP practices that had high levels of Desmospray usage, indicating that it might still be being used for the withdrawn indication of primary nocturnal enuresis. The dictated text did not include any mention of Ferring's initiation of the content.

Ferring stated that whilst it could be argued that the action had a legitimate role in communicating the recent withdrawal of the Desmospray licence for safety reasons, the manner of the unsanctioned activity and the commercial motivation were obviously foremost in its considerations.

Ferring was aware that one hospital generated a letter which was signed by one of the two hospital consultant signatories. However, the letter was not sent to any GP practice as it was withdrawn from the hospital office by a colleague of the same (ex-) representative that had arranged for its creation – the same (ex-) representative that subsequently raised the matter with Ferring.

Ferring was aware that a second letter was requested from the paediatric clinical director at another hospital although no further action was taken in relation to this and no letter was sent.

Across the two hospitals, fifteen practices were identified as potential recipients of the intended letter however no letters were sent from either hospital.

The letter and safety issue were only relevant to urology, hence the activity was isolated to this speciality.

Ferring provided an email from the ex-representative to Ferring and a scanned copy of the handwritten note passed to the ex-representative from the sales manager.

Ferring noted that the ex-representative's email implied that one of its senior managers might be aware of the area sales manager's initiative. Ferring confirmed that during interviews, that senior manager categorically denied any knowledge of the activity. Ferring accepted that the actions of the area sales manager were in breach of Clause 15.2.

The letter would have constituted disguised promotion. However, no letters were actually sent from the hospital and none were received by any GP

practice, Ferring did not believe a breach of Clause 12.1 actually occurred.

Ferring reassured the PMCPA that the area sales manager's actions were not endorsed or approved by Ferring. Ferring aspired to achieve the highest standards of conduct and it submitted it was badly let down by this individual. However, it was unable to interview him/her to determine any missing context and information which might be relevant (a detailed explanation was provided).

Since the matter came to light, Ferring had engaged the services of compliance specialists to work closely with the sales management team to reinforce the importance of securing approval for local initiatives so that they could be appropriately assessed for Code compliance. The entire sales team had also been retrained on the Code and the inappropriateness, in particular, of unapproved local activities.

### PANEL RULING

The Panel noted Ferring's submission that without its consent or approval, an area sales manager had drafted a letter for hospital consultants to send to local GPs recommending the use of DesmoMelt for primary nocturnal enuresis and discouraging the use of Desmospray/desmopressin spray. Desmospray had not been licensed for use in primary nocturnal enuresis since September 2007 (the change in the licence was not recent as stated by Ferring). The drafted text was, in effect, a piece of promotional material.

Regardless of the fact that no letters had been sent to GPs, the provision of the draft text, handwritten on a piece of notepaper, to the hospital consultants meant that they had been handed a piece of disguised promotional material. A breach of Clause 12.1 was ruled.

The Panel considered that the creation of a piece of promotional material by an area sales manager, and its subsequent provision to health professionals, demonstrated an extremely poor understanding of the Code; it appeared that numerous clauses had not been complied with. The Panel considered that the representatives had not maintained a high standard of ethical conduct. A breach of Clause 15.2 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. The Panel noted its rulings and comments above but considered that, on balance, and given the very limited reach of the material at issue (no letters were sent), the area sales manager's conduct was not such as to bring discredit upon, or reduce confidence in, the industry. No breach of Clause 2 was ruled.

**Complaint received**      **26 May 2016**

**Case completed**        **22 July 2016**