

VOLUNTARY ADMISSION BY SERVIER

Conduct of representative

In its response to Case AUTH/1884/8/06, which concerned the conduct of a representative, Servier referred to the inappropriate use of email and the creation and use of letters by the representative. Servier accepted that such conduct was in breach of the Code. As these matters were not the subject of complaint in Case AUTH/1884/8/06 Servier's comments on these points were regarded as a voluntary admission.

The Authority's Constitution and Procedure stated that the Director should treat a voluntary admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take action to address it.

The use of email for promotional purposes without the prior permission of the recipient and the creation and subsequent use of promotional material by a representative were regarded as a serious matters and the Director decided that the admission must accordingly be treated as a complaint.

The Panel noted that the representative had emailed a hospital doctor inviting her to speak at a meeting and suggesting a lunchtime meeting to discuss Protelos (strontium ranelate). A letter to the same doctor sought to rebook a cancelled appointment to discuss 'new evidence behind Protelos, including unique data looking at Non-Vertebral Fractures in the Over 80s... and the long term data'. The letter concluded with 'Would you recommend for patients unable to take the Bisphosphonates, that Protelos is the next option in line with the formulary?' in emboldened type.

Both the letter and email promoted Protelos. The recipient had not given prior permission for receipt of a promotional email and thus a breach of the Code was ruled as acknowledged by the company. The representative had created and disseminated promotional material contrary to Servier's instructions; each piece ought to have been certified and include prescribing information. The representative had not maintained a high standard of ethical conduct: a breach of the Code was thus ruled.

The Panel examined the training materials and noted that the company had not established that the representative had received any relevant training when the initial email was sent.

The Panel considered that on the evidence before it the instructions to representatives about the creation of promotional material and the use of email for promotion purposes were inadequate; a breach of the Code was ruled. High standards had not been maintained. A breach of the Code was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was reserved to indicate particular censure of a company's material or activities.

In its response to Case AUTH/1884/8/06, which concerned the conduct of a representative, Servier Laboratories Ltd referred to the inappropriate use of email and the creation and use of letters by the representative. Such activities were contrary to the company's specific instructions. Servier accepted that such conduct was in breach of the Code. As these matters were not the subject of complaint in Case AUTH/1884/8/06 Servier's comments on these points were regarded as a voluntary admission.

The action to be taken by the Authority in relation to a voluntary admission by a company was set out in Paragraph 5.4 of the Authority's Constitution and Procedure. This stated that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code or if the company failed to take action to address it.

COMPLAINT

The use of email for promotional purposes without the prior permission of the recipient and the creation and subsequent use of promotional material by a representative was regarded as a serious matter and the Director decided that the admission must accordingly be treated as a complaint.

RESPONSE

Servier explained that, despite company instructions not to do so, the representative in question had used email to contact a doctor; the content of at least one of those emails was promotional. This was unacceptable and in breach of Clause 15.2 and also Clause 9.9 as the recipient did not give permission for such use of email.

In addition to email use, and again contrary to specific instructions, the representative had written letters to doctors that were promotional. These letters did not contain prescribing information and were not certified and thus Servier acknowledged a breach of Clause 15.2.

From the in-house training course it was clear that representatives were instructed in a number of acceptable ways of contacting health professionals in hospitals. This instruction did not include the unsolicited use of emails or letters. Servier took all matters relating to the Code very seriously and noted that the representative in question had been disciplined. Any issues identified by the organisation were dealt with quickly and decisively as was evidenced by a bulletin (provided) dated 15 March 2006. Servier therefore did not accept that there had been a breach of Clauses 9.1 and 15.9.

Servier did not believe that the breaches admitted above brought discredit upon, or reduced confidence in, the pharmaceutical industry as it was an isolated

case of an individual acting against clear direction from the company. Servier did not therefore consider that this warranted a breach of Clause 2.

PANEL RULING

The Panel noted that the representative at issue had emailed a hospital doctor inviting her to speak at a proposed meeting and suggesting a lunchtime meeting to discuss Protelos and data about non-vertebral fractures in the over 80s. A letter to the same doctor sought to rebook a cancelled appointment to discuss 'new evidence behind Protelos, including unique data looking at Non-Vertebral Fractures in the Over 80s... and the long term data'. The letter concluded with the question in an emboldened type face 'Would you recommend for patients unable to take the Bisphosphonates, that Protelos is the next option in line with the formulary?'

The Panel noted that both the letter and email promoted Protelos. The recipient had not given prior permission for receipt of a promotional email and thus a breach of Clause 9.9 was ruled as acknowledged by the company. The representative had created and disseminated promotional material contrary to Servier's instructions; each piece ought to have been certified in accordance with Clause 14.1 and include prescribing information. The representative had not maintained a high standard of ethical conduct: a breach of Clause 15.2 was thus ruled.

The Panel noted that whilst the training course discussed contact with health professionals in a hospital environment it did not mention the unsolicited use of email or creation of promotional material by representatives nor did it refer to any other briefing material which might have covered such issues. The training course was undated and it was thus unclear whether it predated the activities at issue or indeed whether the representative in question had received the training. The bulletin dated 15

March 2006 was sent after the email but before the letter. It discussed the 2006 Code and told representatives not to send promotional emails (ie any which referred to a Servier product) to health professionals and, in a separate bullet point, to 'use only materials that had been approved through the regulatory process.' The Panel queried whether it was sufficiently clear that unapproved promotional letters created by representatives should not be used. There was no cross reference to any document which might have addressed the matter. Some might assume that the term 'materials' in the bulletin referred to normal promotional leaflets, detail aids and suchlike rather than a letter seeking an appointment which included promotional claims. The Panel also noted that the company had not established that the representative had received any training on this point when the initial email was sent.

The Panel considered that on the evidence before it the instructions to representatives about the creation of promotional material and the use of email for promotion purposes were inadequate; a breach of Clause 15.9 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was reserved to indicate particular censure of a company's material or activities.

During its consideration of this case the Panel was extremely concerned about the training material and whether it met the requirements of Clauses 2, 9.1, 15.2, 15.4 and 15.9 of the Code. The Panel decided to take its concerns up with Servier as a separate complaint in accordance with Paragraph 17 of the Constitution and Procedure, Case AUTH/1906/10/06.

Proceedings commenced 13 September 2006

Case completed

2 November 2006