

# VOLUNTARY ADMISSION BY ASTRAZENECA

## Arrangements for a meeting

AstraZeneca voluntarily admitted a breach of the Code arising from an internal email to a group of the company's representatives. The email linked the offer of sponsorship to attend an American Urological Association (AUA) meeting to the protection and growth of AstraZeneca's Zoladex (goserelin) business.

The Authority's Constitution and Procedure provided that the Director should treat an admission as a complaint if, *inter alia*, it related to a potentially serious breach of the Code. Linking sponsorship to attend a meeting to the prescription of a medicine was a serious matter and the admission was accordingly treated as a complaint.

AstraZeneca referred to an internal email to representatives which read:

'Finally I can share the outcome from the director's meeting where the business cases for the AUA delegates were reviewed .... In your case the directors felt that taking your customers to the AUA as part of the AZ group would help protect our Zoladex business and in many cases help grow it'. Representatives were asked to pass on an attached invitation although one representative forwarded the whole email to a doctor.

AstraZeneca noted that no meeting of the directors took place for the AUA delegate selection and no director endorsed this method of delegate selection. The directors were not involved in the selection process at all. However, the email clearly implied that the selection criteria for delegates were previous and/or future prescriptions of Zoladex.

The email was certified by two registered signatories who failed to validate the claims therein or question the nature of delegate selection.

The detailed response from AstraZeneca is given below.

The Panel noted with concern that the directors' meeting referred to in the email had not taken place. The email had been certified by two signatories who, according to AstraZeneca, failed to validate the claims therein or query the nature of delegate selection. The email had been sent to representatives one of whom, despite no instructions to do so, had forwarded it to a potential delegate.

The Panel considered that the email inappropriately linked the offer of sponsorship to attend an overseas meeting with past or future prescriptions

of Zoladex. This would certainly be the impression given to representatives and the potential delegate who had received the email. Such an impression was unacceptable. A breach of the Code was ruled. The Panel considered that the provision of the email at issue to a health professional amounted to an inducement to prescribe contrary to the Code; a breach of the Code was thus ruled.

The Panel was extremely concerned that the content of the email demonstrated a lack of awareness of the requirements of the Code by those involved. High standards had not been maintained. A breach of the Code was ruled. The Panel did not consider that overall the email warranted a ruling of a breach of Clause 2 which indicated particular censure and was reserved for such use. No breach of Clause 2 was ruled.

AstraZeneca UK Limited voluntarily admitted a breach of Clause 18.1 of the Code arising from an internal email to a group of the company's representatives. The email linked the offer of sponsorship to attend an American Urological Association (AUA) meeting in the US to the protection and growth of AstraZeneca's Zoladex (goserelin) business.

The action to be taken in relation to a voluntary admission by a company is set out in Paragraph 5.4 of the Constitution and Procedure which states, *inter alia*, that the Director shall treat the matter as a complaint if it relates to a potentially serious breach of the Code. Linking sponsorship to attend a meeting to the prescription of a medicine was a serious matter and the admission was accordingly treated as a complaint.

## COMPLAINT

AstraZeneca stated that the internal email informed the representatives that the company was to invite some of their customers to the AUA meeting; representatives were asked to pass on an attached invitation. The email contained the following: 'Finally I can share the outcome from the director's meeting where the business cases for the AUA delegates were reviewed .... In your case the directors felt that taking your customers to the AUA as part of the AZ group would help protect our Zoladex business and in many cases help grow it'.

This was an erroneous and untrue statement as no meeting of the directors took place for the AUA delegate selection and no director endorsed this method of delegate selection. Indeed, the directors

were not involved in the selection process at all. However, the email clearly implied that the selection criteria for delegates were previous and/or future prescriptions of Zoladex.

Internal investigations established that the following specific selection criteria were applied by the head office brand team:

- Whether the health professional worked in the field of prostate cancer.
- Whether they had an interest in the latest developments in prostate cancer, were likely to apply evidence based logic to their treatment approaches and whether this was relevant to their work.
- Whether they would be interested in an evening session during the conference for AstraZeneca to share its latest survival data.

AstraZeneca explained that on 12 February 2009, a member of staff composed an email for internal use only, to be sent to representatives designed to expedite the delivery of invitations to potential delegates to the meeting. As was evident from the content of the email, the author was keen to get the invites out and replies returned quickly.

The email was certified by two registered signatories who failed to validate the claims in the email or question the nature of delegate selection.

One representative, despite receiving no instruction to do so, forwarded the email to a doctor and potential delegate. The representative then asked the customer to delete the email on instruction from his manager, who had given this instruction on his own initiative.

The email was brought to the attention of AstraZeneca's compliance team, through AstraZeneca's internal reporting system, on 17 February. An internal investigation then began and the following actions taken:

- Individuals involved were managed according to AstraZeneca internal policies.
- It was explained to the health professional who received the email that it was sent in error and was inaccurate and misleading.
- All delegates were told about this mistake and that AstraZeneca would be making a voluntary admission to its regulatory authority.
- Only medical staff from AstraZeneca UK marketing company attended the conference
- Relevant staff were reminded on the content of Clause 18 when arranging such events and that the focus for choosing appropriate delegates must be based upon maximizing patient benefit.

AstraZeneca strove to set the highest of standards and emphasised how seriously it took this failing of its internal procedures and that it considered the contents of the email fell far short of its own high standards as well as those expected by the Code. AstraZeneca was reinforcing the necessary high

standards in undertaking any such educational programmes in the future.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.9 and 18.1 of the Code.

## RESPONSE

AstraZeneca reiterated that the email at issue contained erroneous information about the basis for delegate selection and the involvement of the directors. None of the directors were involved in this matter.

The email implied that the selection of delegates to attend the AUA meeting was based upon 'our Zoladex business'. AstraZeneca noted that if this were true it would have been a breach of Clause 18.1. In reality, selection criteria for delegates were legitimately related to the appropriateness of the meeting to the delegates' area of therapeutic interest except for one, which was their interest in attending an evening meeting at which data on AstraZeneca's product was to be shared. AstraZeneca ensured that this evening meeting did not take place. However, it accepted that delegate selection criteria had already been linked to an interest in its product data and it therefore accepted that there was a breach of Clause 18.1, for which it sincerely apologised.

The email constituted a representative briefing. While technically, the email did not instruct representatives to act directly or indirectly in breach of the Code, AstraZeneca accepted that the briefing implied that AstraZeneca had selected delegates in breach of Clause 18.1. AstraZeneca, therefore, accepted that the email was in breach of Clause 15.9 and apologized for this. Corrective action was taken to ensure that this miscommunication was addressed and all of the representatives involved were contacted to explain the error.

While AstraZeneca admitted breaches of Clauses 18.1 and 15.9 in this instance following the spirit of the Code, it did not consider that it had either failed to maintain high standards or brought discredit upon or reduced confidence in the industry because:

- The email itself was erroneous and did not reflect the actual situation and therefore there was no underlying activity justifying a breach of Clauses 9.1 or 2.
- AstraZeneca had demonstrated that it had effective systems to ensure that employees brought instances of potential Code breaches to the attention of managers and its compliance team and that it would take effective action to deal with those breaches; it was this robust approach that brought the matter to the Authority's attention.
- Immediate and appropriate action was taken, including informing all the delegates involved in

this meeting of AstraZeneca's evaluation of this matter in relation to the Code and the action that it was taking. The delegates were impressed by the high standards and honesty that this demonstrated.

- Only one delegate was sent the email intended for the representatives and there had been no external complaint in relation to it.

These facts, together with the corrective action taken, meant that there was no question that the reputation of the industry had been damaged nor had there been any reduction of confidence in the industry.

AstraZeneca took the Code extremely seriously and undertook every effort to comply with it in both letter and spirit.

### **PANEL RULING**

The Panel noted that the email referred to a directors' meeting at which the business cases for AUA delegates were reviewed and stated that 'the directors felt that taking your customers to the AUA as part of the AstraZeneca group would help protect our Zoladex business and in many cases help grow it'. The Panel noted with concern that the directors' meeting referred to had not taken place. The email had been certified by two signatories who, according to AstraZeneca, failed to validate the claims therein or query the nature of delegate selection. The email had been sent to

representatives one of whom, despite no instructions to do so, had forwarded it to a potential delegate.

Clause 15.9 required that briefing material must not advocate directly or indirectly a course of action which would be likely to lead to a breach of the Code. The Panel considered that the email inappropriately linked the offer of sponsorship to attend an overseas meeting with past or future prescriptions of Zoladex. This would certainly be the impression given to representatives and the potential delegate who had received the email. Such an impression was unacceptable. A breach of Clause 15.9 was ruled. The Panel considered that the provision of the email at issue to a health professional amounted to an inducement to prescribe contrary to Clause 18.1 of the Code; a breach of Clause 18.1 was thus ruled.

The Panel was extremely concerned that the content of the email demonstrated a lack of awareness of the requirements of the Code by those involved. High standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider that overall the email warranted a ruling of a breach of Clause 2 which indicated particular censure and was reserved for such use. No breach of Clause 2 was ruled.

**Complaint received**      **6 May 2009**

**Case completed**      **12 June 2009**

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