CASE AUTH/1899/10/06

EX-EMPLOYEE/THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY v ASTRAZENECA

Representative call rate frequency

The Medicines and Healthcare products Regulatory Agency forwarded a complaint from an ex-employee of AstraZeneca about representative call frequency targets in relation to the promotion of Casodex (bicalutamide). An AstraZeneca oncology sales and marketing booklet showing activity targets was provided, together with a company email explaining the call frequency targets for employees.

The complainant stated that the intensity of the campaign was such that main target doctors had to be called upon once a month. The carrot to achieve this frequency was the AZpiration scheme. Points for frequency could be exchanged for prizes, essentially an inducement to breach the Code.

During 2004 and the first 6 months of 2005 the oncology team was under extreme pressure to achieve, *inter alia*, (in 2004) 12 face to face calls a year on their main group of target customers. The complainant referred to two previous cases (Cases AUTH/1714/5/05 and AUTH/1737/7/05) which had involved AstraZeneca and call rates. Both complainants were anonymous and made comments about the culture at AstraZeneca.

If the carrot in the form of the AZpiration scheme failed to induce representatives into breaking the Code then a stick in the form of short term performance measures was threatened. This was viewed as the first step in a disciplinary process. This was a threat which could be used (formally and informally) and indeed was used to bully and harass representatives into achieving the frequency of 12 face to face calls. This amounted to harassment to break the Code.

The complainant noted that during 2004 and 2005 over 70% of the oncology team left AstraZeneca as they thought they were no longer working for an ethical company and were bringing the industry into disrepute. Many customers complained. Oncologists specialising in breast and prostate cancer would be targeted 36 times a year by the company.

The complainant alleged that AstraZeneca was able to break the Code for 18 months with regard to call frequency because a culture of bullying and harassment was introduced. The honest, open, supportive culture was changed to one where trust and confidence were deliberately destroyed with the appointment of two new senior executives. A witness statement from a separate matter stated 'There were presentations where everyone in the audience felt intimidated. Made to feel a bunch of failures, things were going to change, better toe the line'. A meeting in Ashby-de-la-Zouch in August 2004 was an example of this behaviour towards the breast oncology team.

The Panel noted that the complainant had referred, *inter alia*, to Case AUTH/1714/5/05 wherein it was alleged that AstraZeneca's psychiatry representatives were incentivised to see 90% of customers 16 times a year, 12 face to face meetings and 4 times at meetings. The Panel had noted, *inter alia*, that AstraZeneca had acknowledged that there might have been activity out of line with the supplementary information to the Code. This would be a consequence of following the campaign notes. Breaches of the Code had been ruled and no breach of Clause 2.

The Panel considered that the allegations about call rates and incentivisation were closely similar to those in Case AUTH/1714/5/05 and the rulings in that case applied here. Breaches of the Code were thus ruled. No breach of Clause 2 was ruled. In addition the Panel ruled a breach of the Code because the representatives' briefing material advocated a call rate that was likely to lead to a breach of the Code.

In relation to the allegations about comments made by a senior sales executive at a meeting the Panel noted that the company accepted that in hindsight the tone of the meeting was perhaps too critical. The slides provided did not appear unreasonable; however there were no speaker notes nor was a transcript of the meeting available. It was thus not possible to determine whether what had been said at the meeting amounted to a breach of the Code. No breach was ruled.

The Medicines and Healthcare products Regulatory Agency (MHRA) forwarded a complaint from an ex-employee of AstraZeneca UK Limited, about representative call frequency targets in relation to the promotion of Casodex (bicalutamide). An AstraZeneca oncology sales and marketing booklet showing activity targets was provided together with a company email explaining the call frequency targets for employees.

COMPLAINT

The complainant stated that the intensity of the campaign was such that frequency of calling on their main target doctors of once a month was demanded. The carrot to achieve this frequency was the AZpiration scheme. Points for frequency could be exchanged for prizes, essentially an inducement to breach the Code.

During 2004 and the first 6 months of 2005 the

oncology team was under extreme pressure to achieve metrics which included (in 2004) 12 face to face calls a year on their main group of target customers. Representatives tried to raise their concerns about achieving these metrics and staying within the Code via their union representative. Concern was raised at all levels of management. The representatives did not receive any advice. It was mentioned at a management group that they were breaching the Code. Their concerns were not escalated as a management team because they were in fear of losing their jobs.

The complainant noted two cases involving AstraZeneca (Cases AUTH/1714/5/05 and AUTH/1737/7/05) had involved call rates. Both complainants were anonymous stating '… if one raised this with AstraZeneca, it would not make any difference and would be a career-limiting move' and 'This fear culture also prevented the complainant from revealing his/her identity. Reprisals would be severe and covert'. The Panel had queried whether it was appropriate to give representatives targets to meet objectives over which the Panel considered they should have little influence.

If the carrot in the form of the AZpiration scheme failed to induce representatives into breaking the Code then a stick in the form of short term performance measures was threatened. This was viewed as the first step in a disciplinary process. This was a threat which could be used (formally and informally) and indeed was used to bully and harass representatives into achieving the frequency of 12 face to face calls. This amounted to harassment to break the Code.

During 2004 and 2005 over 70% of the oncology team left AstraZeneca as they thought they were no longer working for an ethical company and were bringing the industry into disrepute. Many customers complained. Oncologists specialising in breast and prostate cancer would be targeted 36 times a year by the company (12 x Faslodex, 12 x Arimidex and 12 x Casodex/Zoladex).

The complainant alleged that AstraZeneca was able to break the Code for 18 months with regard to call frequency because a culture of bullying and harassment was introduced. The honest, open, supportive culture was changed to one where trust and confidence were deliberately destroyed from January 2004 with the appointment of two new senior executives. A witness statement for a separate matter stated 'There were presentations where everyone in the audience felt intimidated. Made to feel a bunch of failures, things were going to change, better toe the line'. A meeting in Ashby-de-la-Zouch in August 2004 was an example of this unwanted behaviour towards the breast oncology team. The company should have a transcript or tape of the meeting.

The complainant claimed to have a wealth of documents to back these allegations.

When writing to AstraZeneca the Authority asked it to respond in relation to Clauses 2, 9.1, 15.4 and 15.9 of the 2003 edition of the Code.

RESPONSE

AstraZeneca explained that in early 2006 a member of the urology sales team had made various allegations against the company. Some of these matters were the subject of an ongoing legal dispute. One of the allegations, AstraZeneca believed, formed the basis of this complaint ie that call frequency targets set in 2004 and early 2005 were in breach of the Code and that there was a culture of inducement or harassment to breach the Code in that regard.

AstraZeneca noted that in May 2005 it had received a complaint (Case AUTH/1714/5/05) the essence of which was that the company was setting call frequency rates so high as to induce a breach of the Code and, in particular, requiring its representatives to over call on customers; that representatives were actively incentivised to breach the Code under the AZpiration scheme; that failure to comply with targets would adversely affect pay and promotion prospects and that raising concerns would be career-limiting. Breaches of Clauses 15.4 and 9.1 of the Code were ruled.

In July 2005 AstraZeneca received another complaint (Case AUTH/1737/7/05) that a senior executive had encouraged overcalling on customers in breach of the Code, and that a 'fear culture' existed within AstraZeneca. AstraZeneca was ruled in breach of Clauses 15.9 and 9.1 of the Code.

In both cases AstraZeneca accepted the rulings and put in place a comprehensive and detailed package of measures details of which it provided. In neither the investigations themselves nor the Panel's rulings were the allegations concerning a 'fear culture' at AstraZeneca supported.

The basis of the current complaint (Case AUTH/1899/10/06) was the rulings from Cases AUTH/1714/5/05 and AUTH/1737/7/05. Indeed, these were expressly referred to by the complainant. However, for clarity the following specific allegations, all relating to 2004 and early 2005, were made:

- Once a month calling on target doctors and 12 face to face calls on target customers.
- AZpiration scheme – points for frequency essentially an inducement to break the Code.
- Concerns raised with union representatives and at all levels of management and no advice given.
- Representatives threatened with disciplinary action if they failed to achieve the frequency targets and a general culture of bullying and harassment.
- Presentation by a senior sales executive in August 2004 which intimidated the audience.

In AstraZeneca's view the current complaint clearly concerned a matter closely similar to one which had been the subject of a previous adjudication and so the Director should exercise her discretion under Paragraph 5.1 of the Constitution and Procedure and not proceed with it.

AstraZeneca's reasons for not proceeding were:

- No new evidence had been adduced by the complainant.

There were only two points of substance that were different with the current case and Cases AUTH/1714/5/05 and AUTH/1737/7/05. The first was that Case AUTH/1714/5/05 focused on the AstraZeneca psychiatry team rather than the oncology sales team. However, in practice, the investigations conducted by AstraZeneca, the responses made to the Authority and the remedial action taken by the company did not focus only on psychiatry. The second difference related to the presentation in August 2004 and AstraZeneca's separate response to this was set out below. However, AstraZeneca believed the complaint about this meeting did not relate to an actual or potential Code breach and therefore was not something the Authority would ordinarily investigate.

- Passage of time or change in circumstances raised doubts as to whether the same decision would be made in respect of the current complaint.

The substance of the complaint related to fundamentally the same activities and materials as the previous cases. It was not possible to see how the passage of time or change in circumstances could therefore have any bearing on the conclusions reached. One element of this complaint was that concerns were raised with union representatives and at all levels of management but that no advice was given. This lack of clarity had however already been acknowledged as part of the response to Case AUTH/1714/5/05 where the company accepted that there might have been activity out of line with the requirements of the supplementary information to Clause 15.4 and in the response to Case AUTH/1737/7/05 where it was stated that, '[the senior executive] was open with the fact that he had not [in the past] provided clarity around achieving call frequency within the ABPI Code of Practice. This was followed by explicit instruction on how this could be achieved'.

- The complaint covered matters similar to those in a decision of the Panel, which was not appealed.

AstraZeneca took corporate governance and compliance with the Code very seriously as restated in various submissions. It did not appeal the previous adjudications for this reason. AstraZeneca therefore felt that it would be inequitable to prejudice its position now by proceeding with the current case simply due to its decision not to appeal the previous rulings. The potential danger of following such a course would be that companies would be compelled to appeal all decisions to preserve their arguments under Paragraph 5.1.

With regard to the complainant's statement that during 2004 and 2005 over 70% of the oncology team left AstraZeneca as they thought they were no longer working for an ethical company and bringing the industry into disrepute, AstraZeneca noted that records showed that the number leaving the oncology sales force in 2004 was similar to the attrition rates across the business. More people (far below 70%) left in 2005 but this followed a significant reorganisation of the team in 2004. In addition, no-one in the oncology team gave, as a reason for leaving, 'no longer working for an ethical company and bringing the industry into disrepute', and no leavers stated they were leaving due to a culture of 'bullying and harassment'. However, approximately 10% of leavers stated they were 'unhappy with management style' and 20% stated they were 'unhappy with the environment'. Neither of these reasons were unusual considering the realignments ongoing in the oncology teams.

AstraZeneca noted that the Authority had asked it to respond to the allegations made but it believed that this case should not proceed pursuant to Paragraph 5.1 of the Constitution and Procedure, for the reasons set out above. It should also be considered that all of the remedial action already undertaken by AstraZeneca in response to the previous cases would address the issues raised in this complaint, some of which were outlined below.

Measures had included:

- The sales force incentive scheme was no longer linked to frequency of calling on individual customers. The current incentive scheme was based on sales measures such as market share or volume growth. The only customer facing metric for the oncology sales team was that of attendance of customers at meetings and this constituted a small proportion of the total possible bonus (<20%). Total call volume was a metric option used for the primary care sales force and this constituted a small proportion of the total possible bonus (<20%).
- All representatives were comprehensively trained on the Code.
- All internal meetings involving representatives now included five mandatory slides summarising key Code's requirements. The requirement that only three unsolicited calls per representative, per customer, per year were allowed was explicitly highlighted.
- AstraZeneca had developed an emphasis on call quality, over quantity. This was reflected in its incentive schemes as well as in the delivery of presentations by the company's senior management.
- Activity targets had been revised to ensure that no customer received more than 3 unsolicited calls per year and all calls were logged within a database, including details of whether the call was solicited or unsolicited.

With regard to corporate culture the company had:

- Established a corporate reputation group and increased emphasis on an open, honest culture throughout the business. The Code and corporate compliance had a high profile within the company with a variety of measures instituted since the Code breaches in 2005.
- In mid-2005 all managers attended a meeting on compliance and company vision during which the details of the breaches of the Code in Case

AUTH/1714/5/05 were shared. These messages were cascaded to the sales force in subsequent meetings. A renewed vision based on 'Winning the Right Way' was developed together with four strategic cornerstones to drive a culture of intelligent compliance.
- All staff were formally trained on the Code and the AstraZeneca Code of Sales and Marketing Practice. All new starters had to read, pass a small test and acknowledge that they would abide by all AstraZeneca's codes within 1 month of joining the company. A record was kept of all non-compliers and reported monthly in the director's governance report so that the directors could investigate if individuals required further support.
- In early 2006, when the new Code was launched, all representatives received a CD Rom and guidance booklet highlighting the main changes to the Code.
- Annually, all representatives renewed their commitment to AstraZeneca's policies (including the Code) and a register was kept of their recommitment.
- All staff could raise concerns about compliance in confidence at any time through several different channels including contacting the line manager, another senior manager within the organisation, the UK compliance officer or at corporate headquarters or employee relations.

With regard to the presentation in August 2004 where the complainant alleged that everyone in the audience felt intimidated, AstraZeneca explained that during 2004 the oncology team was significantly restructured. There were several new managers appointed. In addition, in 2004, a new selling model was introduced to improve in-call performance. These organisational changes unsettled some members of the oncology sales force, especially those who had been working under the previous management team and structure for many years.

In August 2004, the AstraZeneca breast team held a full-day meeting in Ashby-de-la-Zouch. This meeting was not recorded, so no transcript was available of what was said, but AstraZeneca had established the following:

- The meeting ran from approximately 10am until 3.30pm.
- Attendees included all breast sales representatives, oncology sales managers, members of the head office breast cancer brand team and relevant staff from the learning and development team. The urology sales force was not involved.
- The purpose of the meeting was to share the results of some market research that had evaluated the impact of the breast sales team interactions with their target customers.
- The meeting included a presentation which overviewed the poor performance of the team with respect to recall of key messages by their target customers. This was to challenge and motivate a group of talented, well-paid representatives to raise their level of performance.
- The focus of the presentation was on the quality of the interactions, not on the frequency of calls on individual customers.
- The day also included small group workshops to brainstorm potential solutions which were led by sales managers.
- The day included validation of the representatives against the AstraZeneca selling model to evaluate the standard of the representatives. This was led by the learning and development function, with support by sales managers.

From the accounts of attendees it was evident that the meeting held in August 2004 had not entirely met its objective of challenging and motivating the breast oncology sales force. In hindsight, the tone of the meeting was perhaps too critical. However, the meeting focussed on the quality of interactions and on customer message recall in order to improve performance, not on the issues surrounding the frequency of calls on individual customers.

PANEL RULING

The Panel noted that the complainant had referred, inter alia, to Case AUTH/1714/5/05 wherein it was alleged that AstraZeneca's psychiatry representatives were incentivised to see 90% of customers 16 times a year, 12 face to face meetings and 4 times at meetings. The Panel had noted, *inter alia*, that AstraZeneca had acknowledged that there might have been activity out of line with the supplementary information to Clause 15.4 of the Code. This would be a consequence of following the campaign notes. Thus the Panel had ruled a breach of Clause 15.4. The Panel considered that AstraZeneca had not maintained high standards. A breach of Clause 9.1 had been ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure.

The Panel considered that the allegation in the present complaint, Case AUTH/1899/10/06, about call rates and incentivisation was closely similar to those considered in Case AUTH/1714/5/05. AstraZeneca had invited the Director to exercise the discretion given to her under Paragraph 5.1 of the Constitution and Procedure to decide not to proceed with Case AUTH/1899/10/06. The Panel noted that Paragraph 5.1 of the Constitution and Procedure provided, *inter alia*, that if a complaint concerned a matter closely similar to one which had been the subject of a previous adjudication the Director should normally allow it to proceed if it was not the subject of an appeal to the Appeal Board. Case AUTH/1714/5/05 had not been subject to an appeal to the Appeal Board and the Director had thus decided to allow the present case to proceed.

The Panel was thus obliged to consider the matter. The Panel considered that the allegations about call rates and incentivisation were closely similar to those in Case AUTH/1714/5/05 and the rulings in that case applied here. Breaches of Clauses 9.1 and 15.4 were thus ruled. No breach of Clause 2 was ruled. In addition the Panel ruled a breach of Clause 15.9;

the representatives' briefing material advocated a call rate that was likely to lead to a breach of the Code.

In relation to the allegations about comments made by a senior executive at a meeting the Panel noted that the company accepted that in hindsight the tone of the meeting was perhaps too critical. The slides provided did not appear unreasonable; however there were no speaker notes nor was a transcript of the meeting available. It was thus not possible to determine on the balance of probabilities whether what had been said at the meeting amounted to a breach of Clauses 15.4 or 15.9; no breach of these clauses was accordingly ruled.

Complaint received	**11 October 2006**
Case completed	**19 January 2007**