CASE AUTH/2866/8/16

ANONYMOUS, NON CONTACTABLE v ASTRAZENECA

Engagement of a consultant and his/her training and consultancy company

An anonymous, non-contactable complainant raised concerns about a therapy area specific training and consultancy company and its owner, a health professional who delivered services including practice audits, health professional mentoring, education and classroom based training workshops funded by a number of named pharmaceutical companies including AstraZeneca. These services had been delivered in a number of named clinical commissioning groups (CCGs) in one area. In addition, the health professional was a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation the health professional had prescribing responsibility and influence within one of the CCGs named by the complainant.

The complainant alleged that the training and consultancy company had conducted industry funded clinical audits in several GP surgeries in the area in question which were identifiable as they had highly irregular use of the sponsoring company's product. The patients of several surgeries in one CCG were either initiated onto or switched to the sponsor's medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical company which had funded the training and consultancy company.

The complainant referred to a series of accredited training workshops delivered by the training and consultancy company in partnership with a named CCG which was completely funded by industry. The complainant was concerned about the potential substantial financial support to the training and consultancy company for these workshops due to reservations about the ethics of that organisation and because its owner was directly contracted to the local city based CHO. In the complainant's view industry's financial support for these courses was staggering and could be perceived as an attempt to 'buy the business'.

The complainant alleged that the training and consultancy company had told pharmaceutical companies that if they failed to provide support, their products would not be used in the CCG in which he/she had prescribing responsibility. The complainant stated that his/her company's local representative felt highly pressured to offer funding as he/she had been threatened that if he/she failed to support training events the health professional in question would simply get the money from another pharmaceutical company. The complainant stated that this highly coercive behaviour was completely unacceptable and he/she assumed that similar pressure had been exerted on other pharmaceutical companies. In addition the complainant noted that services provided by industry were in some cases very similar to the offerings developed by the training and consultancy company and alleged that the health professional in question had left individuals in no doubt that if their company attempted to partner in CCGs where he/she wanted to deliver programmes there could be consequences for their sales in the area in which he/she had prescribing responsibility.

The detailed response from AstraZeneca is given below.

The Panel had no contact details for the complainant and so could not ask him/her for further details. The complainant had the burden of proving his/her complaint on the balance of probabilities; he/she had not provided any evidence in support of the allegations.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company and subsequently referred to its owner. In this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the scope of the complaint included the engagement of the health professional in question and/or the activities of his/her company with health professionals, whether the company's activities were delivered by its owner or other individuals. However, when considering such matters the totality of a pharmaceutical company's interactions with the health professional in question would nonetheless be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company which named the health professional in question as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional was contracted by the NHS to work at a number of GP surgeries in addition to his/her role at the city based CHO.

In addition the Panel noted that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred.

The Panel noted that according to AstraZeneca it had sponsored only one, one day meeting run by the training and consultancy company which was held in October 2014. The Panel was very concerned that the form authorising electronic payment to the training and consultancy company for this meeting was signed as approved by the named health professional rather than, as required, by the representative. This was apparently not noted at the time by the representative and/or line manager responsible for overall review and

approval of the meeting. However, the Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breaches of the Code were ruled including no breach of Clause 2. These rulings were made under the 2014 Code.

The Panel noted that AstraZeneca had engaged the named health professional 54 times between May 2014 and June 2016 as a speaker and twice as a chairman at its lunchtime or evening promotional meetings. In addition, the named health professional had been engaged 5 times between May and November 2015 as a speaker on its Expert on Demand Programme.

The Panel noted that although AstraZeneca referred to the appointment of the named health professional as an individual, the fee for service contracts showed that the fees were in fact paid to the training and consultancy company.

The Panel noted that according to AstraZeneca's standard operating procedure (SOP) written director approval was needed before contracting with a health professional service provider for any further employment over 20 engagements, or over a stated monetary amount, in a 12 month period. There was no evidence before the Panel to show that in relation to the 29 speaker meetings and 5 Expert on Demand engagements in 2016 such approval had been sought. The Panel noted the fees actually paid by AstraZeneca in 2015 and 2016. It appeared to the Panel that particularly for the meetings held at GP practices which comprised one presentation of an hour or less the monies paid exceeded the values in the company's fair market value speaker fees table. There was no evidence before the Panel that there had been written justification and/or signatory approval of the fees as required by the relevant SOP.

The Panel noted AstraZeneca's submission that it had engaged the named health professional because of his/her experience, knowledge and availability, and as he/she was not an NHS employee he/she was available for daytime meetings as he/she was not subject to restrictions on speaking at industry-led promotional daytime meetings. The Panel noted that, nonetheless, he/she had also been engaged to speak at evening meetings.

The Panel noted that according to AstraZeneca its representatives did not feel pressurised to select the named health professional as a speaker and that he/she did not identify practices to receive these meetings. The Panel noted the high level of contact between representatives and the named health professional at various surgeries in addition to contact at the speaker meetings. The customer relations management (CRM) entries did not show whether such contacts were solicited or unsolicited. The CRM entries showed that on occasion such contacts included discussion of educational needs. The Panel noted AstraZeneca's submission that CRM references to 'mapping out practices' and 'further surgeries to consider' referred to the named health professional's availability to speak rather than practice selection.

The Panel noted AstraZeneca's submission that it was not normal practice for the company to engage a speaker 56 times over 2 years within a relatively small geographical area. The named health professional had spoken more than once at a number of GP practices. The company stated that it first became aware of the high use of the named health professional before it was notified of this complaint but did not state what had triggered this.

The Panel noted that paragraph 2 of the fee for service speaker contracts stated that the consultant confirmed that he/she did not interpret the engagement as an incentive or reward for past, present or future willingness to or as an inducement to, *inter alia*, prescribe or recommend AstraZeneca's product or to secure any improper advantage for the company. Paragraph 5 provided that the speaker acknowledged that he/she had been selected to provide the services because of his/her expertise in the relevant subject matter.

In relation to the speaker meetings whilst it had concerns about the company's governance of the activities and materials the Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional/the training and consultancy company was an inducement to prescribe as alleged. No breach of the Code was ruled.

In relation to the Expert on Demand Programme the Panel noted that this was a promotional programme whereby experts delivered 30 minute on line presentations. The named health professional had delivered 5 such meetings in 2015 and had been paid for each. Section 2 of the fee for service contract for the Expert on Demand Programme, dated 28 January 2015 stated that the named health professional did not interpret this engagement as an incentive or reward or an inducement to, *inter alia*, recommend or prescribe any AstraZeneca product. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement was an inducement to prescribe. No breach of the Code was ruled.

The Panel noted its comments above regarding the fees paid to the named health professional/ the training and consultancy company. It also noted the number of speaker engagements and considered that when an individual/organisation was so engaged it was beholden upon the company to ensure that all aspects of the arrangements stood up to scrutiny and otherwise complied with the Code. Despite its high use of the named health professional over 2 years, AstraZeneca only became aware of such usage in July 2016, even though such usage was not in accordance with the company's policies and procedures. The impression created both externally and internally by such arrangements

should be borne in mind. The Panel also noted the high number of representative contacts with the named health professional at various local practices. It did not appear that the company had exercised due diligence in its multiple engagements of the named health professional. Such engagements were not in accordance with the relevant SOPs. In this regard, high standards had not been maintained. A breach of the Code was ruled.

The Panel, however, did not consider that the complainant had established a breach of Clause 2 and no breach was ruled accordingly.

In relation to medical and educational goods and services, there was no evidence before the Panel that AstraZeneca had engaged in any relevant activity. No breach of the Code was thus ruled.

An anonymous, non-contactable complainant who described themselves as an employee of one of the many manufacturers of therapies in a particular therapy area, complained about the conduct of a therapy area specific training and consultancy company run by a named health professional, that delivered a range of services to, *inter alia*, the NHS including services that were funded by a number of named pharmaceutical companies including AstraZeneca.

COMPLAINT

The complainant stated that the named health professional, in addition to his/her role at his/her company was also a specialist nurse employed on a contractual basis by a number of NHS organisations including a city based community healthcare organisation (CHO). In his/her role as a nurse within that organisation he/she had prescribing responsibility and influence within a named clinical commissioning group (CCG) area. The services offered ranged from in practice audits, health professional mentoring and education, to classroom based training workshops. These offerings had been delivered in a number of named local CCGs. Funding was provided for these initiatives through various mechanisms within the Code ie independent stand meetings.

The complainant stated that he/she had previously raised concerns within his/her organisation in relation the legitimacy of the training and consultancy company business model, in particular how it received funding from the pharmaceutical industry which unfortunately included on-going financial and logistical support from the complainant's own company. The complainant's concerns had been raised internally with management but no action had been taken to rectify the situation and the complainant believed that his/her job would be at risk if his/her confidentiality in raising these issues was not protected.

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. The pattern of disproportionate increases in product sales could be directly linked back to the pharmaceutical companies' funding support to the training and consultancy company. The complainant explained that unfortunately to protect his/her anonymity, he/she was unable to provide a very detailed narrative but would endeavour to give enough information so that the training and consultancy company and the pharmaceutical companies that used it were held to account.

The complainant stated that at the beginning of 2016 the training and consultancy company started to deliver a series of training workshops in partnership with the CCG in which the named health professional had prescribing responsibility which were accredited by the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN). The delivery of the workshops was, and continued to be completely funded by industry. The complainant articulated his/her concerns to his/her line manager regarding the company potentially providing substantial financial support to the training and consultancy company for these workshops due to his/her reservations about the ethics of that organisation and because its owner was directly contracted to the city based CHO.

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try to dissuade his/her company from being involved. Unfortunately the concerns the complainant foresaw had materialised into major conflict of interest and anti-competitive issues whereby the training and consultancy company had told potential industry partners that if they failed to provide support, their products would not be used in the CCG in which the complainant stated that the named health professional had prescribing responsibility and influence. The complainant stated that his/her company's local representative felt highly pressured to offer the training and consultancy company funding as the individual had been threatened that if he/she failed to support training events the named health professional would simply get the money from another pharmaceutical company. According to the complainant this was highly coercive behaviour and clearly completely unacceptable and one could only assume that similar pressure had been exerted on all other pharmaceutical companies.

An additional issue that recently came to light was that most of the organisations working in the therapy area provided a range of industry-developed services that were deployed in partnerships with NHS organisations; these services were in some cases very similar to the offerings developed by the training and consultancy company. The named health professional had left individuals in no doubt that if their organisation attempted to partner in CCGs where he/she wanted to deliver the programmes there could

be consequences for their sales in the area in which he/she had prescribing responsibility.

In the complainant's view the NHS and industry should be able to collaborate in highly transparent projects that benefited all stakeholders. Having to turn to the PMCPA to whistle-blow on his/her own organisation and the unacceptable behaviour of an organisation that it was actively engaged with was the low point of his/her career in the pharmaceutical industry. The complainant stated that the cavalier attitude of management within his/her own organisation and an inability for him/her to sit on the side-lines as the actions of a few undermined those of many and once again brought the industry into disrepute was too much to stomach. The complainant felt incredibly disillusioned that the industry and his/her company continued to work alongside an organisation that operated in a manner that was simply unacceptable in 2016. Unfortunately, industry was not an innocent party in the affair; all of the companies that had been involved with the training and consultancy company needed to reassess how they conducted business. The complainant appreciated that the evidence given in the complaint might not be detailed enough for the Authority to act but he/she hoped that there was enough information to at least investigate the relationship between the named health professional and a number of pharmaceutical companies. The great shame was that he/she might well be delivering much needed training and support for health professionals, however, the path he/she had decided to follow to extract financial support from industry had sullied what could have otherwise been a noble endeavour. The complainant hoped his/her complaint was seen as a genuine cry for help from the PMCPA as he/she had been ignored by those in positions of power within his/her organisation. The complainant stated that this complaint was motivated by a strong desire to do what was right; he/she was reasonably certain that if the issues outlined were investigated and his/her position within his/her company and probably the industry would become untenable.

The complainant provided a website address for the training and consultancy company.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 of the Code with regard to the clinical audit and with regard to training workshops delivered in partnership with a named clinical commission group (CCG). The case would be considered under the requirements of the Code relevant to the time the activities took place. The clause numbers cited above were relevant to the 2015 and 2016 Codes.

RESPONSE

AstraZeneca submitted that it took its obligations to comply with the Code seriously and had investigated the points raised and paid particular attention to its relationship with the training and consultancy company and the named health professional.

AstraZeneca submitted that the scope of its investigation included all AstraZeneca engagements of the named health professional and/or the training and consultancy company which had occurred between 13 May 2014, the date of its first engagement of the named health professional and 3 August 2016 – the date AstraZeneca was notified of this complaint.

Clinical audits

AstraZeneca submitted that it had not provided funding to the training and consultancy company or the named health professional to conduct any clinical audits. Therefore, it denied breaches of Clauses 19.1 or 19.2 of the Code with respect to its involvement with the training and consultancy company.

Accredited training workshops

AstraZeneca submitted that it had not funded any training workshops delivered by the training and consultancy company or the named health professional in partnership with the CCG in which he/she had prescribing responsibility.

AstraZeneca sponsored one workshop delivered by the training and consultancy company at which it had a stand, in October 2014. AstraZeneca understood that two other pharmaceutical companies also sponsored that meeting. A copy of the flyer for the workshop, a copy of the agenda and details of the nature of the funding were provided. AstraZeneca submitted that it did not influence or create the content of the workshop so neither the agenda nor the flyer was certified or examined by AstraZeneca. In compliance with AstraZeneca policies and procedures, the proposed sponsorship was reviewed and approved by the manager of the representative who organised the sponsorship before the workshop occurred.

AstraZeneca's use of the named health professional and the training and consultancy company

AstraZeneca submitted that it engaged the named health professional 56 times between 13 May 2014 and 3 June 2016 at face-to-face AstraZeneca promotional meetings. At fifty-four of the meetings the named health professional provided a speaker service and at two, he/she chaired the meeting.

The named health professional was selected to provide these services due to his/her experience as a specialist nurse in primary care, his/her knowledge of the current management of a particular condition and his/her availability to speak at lunchtime meetings. Representatives interviewed during the investigation stated that while there were other suitable health professional speakers, they were NHS employees and unable to speak during normal business hours due to prohibitions in their NHS contracts. In contrast, while the named health professional provided services to the NHS, he/she was not an NHS employee during the relevant time period and thus, not subject to restrictions on speaking at industry-led promotional lunchtime meetings.

A written contract was agreed with the named health professional before services commenced, which specified the nature and scope of those services and basis for payment. These engagements complied with the requirements of Clause 23.1. The titles and dates of these meetings, as well as the honoraria paid to the named health professional, were provided.

AstraZeneca submitted that the named health professional also spoke five times between 6 May 2015 and 18 November 2015 on its Expert on Demand Programme. This was an AstraZeneca funded promotional programme in which experts delivered thirty minute presentations at virtual meetings via WebEx to health professionals using slides developed and certified by AstraZeneca. They participated in mandatory web conference training which covered the content of the slides before speaking at any meetings. The programme was managed by an external third party which was responsible for scheduling the meetings, arranging the contracts and paying the speakers.

AstraZeneca executed a written contract with the named health professional before services commenced in relation to this programme, which specified the nature, and scope of his services and basis for payment. These engagements complied with the requirements of Clause 23.1. The topics and dates of these meetings, as well as the honoraria paid to the named health professional, were provided. The named health professional was also paid an honoraria for attending a training session on slide content on 12 February 2015.

In the interests of full disclosure, AstraZeneca declared that it had not engaged a named employee of the training and consultancy company, to provide services in any capacity between 1 January 2014 and 3 August 2016.

AstraZeneca had not contracted the training and consultancy company to provide any type of services on its behalf and so Clause 21 was not relevant.

AstraZeneca concluded that it took its compliance with industry Codes of Practice very seriously, and believed that its activities complied with Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1.

In response to the Panel's request for further information, AstraZeneca made the following points.

Clinical audits

AstraZeneca stated that it did not directly fund a practice or group of practices to carry out audits/ reviews independently of AstraZeneca in three named CCGs or in a named region between 1 January 2014 to 3 August 2016.

AstraZeneca stated that it had not funded any activity provided by the training and consultancy company which might be described as a nurse-led review or clinic.

Meetings

Copies of contracts with the named health professional were provided and a revised copy of a table listing speaker meetings updated to include meeting numbers and thus allow cross-referencing. Copies of the agendas (showing venues) for meetings conducted by the named health professional were also provided.

Copies of the AstraZeneca Ethical Interactions (EI) standard operating procedure (SOP) and the AstraZeneca Salesforce Meetings Compliance Guide were provided which detailed AstraZeneca's approval and governance processes for such meetings. In brief, the approval process involved:

- Representatives provided their line managers with an agenda, proposed venue, hospitality breakdown, speaker contract and proposed honorarium, as well as slides to be used
- Line managers reviewed this information for compliance with the SOP and other relevant guidance and ensured that representatives made any necessary changes to ensure compliance before they approved the meeting.
- The signatories reviewed any slides to be presented, if they were not all pre-approved. Historically speaker slides were examined by signatories. Following a previous undertaking to the PMCPA in 2016, all speaker slides were now formally certified.

AstraZeneca had in place a suite of governance and monitoring processes around such meetings. Among these, line managers were required to attend at least one promotional meeting each quarter to verify compliance. Any instances of non-compliance were reported to its compliance officer who reviewed them, submitted them to the company's compliance monitoring system, reported on them to the senior management team at quarterly local compliance committee meetings and recommended additional training and/or sanctions, if appropriate. Further, AstraZeneca had a meetings compliance dashboard which summarised compliance data for various types of meetings which were reviewed regularly and disseminated throughout the organisation to enhance compliance and identify training needs. In addition, AstraZeneca's global compliance assurance partner reviewed a sample of promotional meetings annually.

AstraZeneca reiterated that the named health professional was selected to speak at AstraZeneca meetings in a particular region because he/she:

- had broad, relevant experience as a specialist nurse in primary care
- had a comprehensive knowledge of the current management of patients
- was available to speak at daytime meetings. While there were other suitable health professional speakers, they were NHS employees and unable to speak during normal business hours. In contrast, he/she was not an NHS employee and thus not subject to restrictions on speaking at industry led promotional daytime meetings.

AstraZeneca did not normally engage a speaker 56 times over 2 years within a relatively small geographical area. AstraZeneca's SOP described restrictions on the number of occasions an individual might be engaged and the maximum permitted spend per individual.

AstraZeneca was first aware of the high usage of the named health professional on 13 July 2016. On 15 July the sales force was instructed not to plan any further use of the named health professional. Information on the 31 uses of, and the amount paid to, the named health professional was then presented at the local compliance committee at its quarter 2 2016 meeting.

While AstraZeneca recognised that the usage threshold for the named health professional was exceeded on this occasion a clear policy was in place and a communication to prevent further engagements with him/her was issued as soon as this high usage had been identified. Through this investigation the company had identified areas of improvements within its existing procedures including monitoring usage on a more frequent basis so as to identify high frequency engagements earlier and further guidance on geographical distribution of usage with high frequency engagements.

With regard to the number of times a speaker could be engaged under a contract, AstraZeneca's normal practice was to enter into a separate contract for each engagement. The Expert on Demand program, where all multiple engagements were covered by a single contract, was an exception.

The need for meetings was identified locally by representatives based on educational need and level of interest, as expressed by individual practices. Representatives also identified practices using publicly available data on the number of uncontrolled relevant patients under a practice's care. During the course of the investigation into this matter representatives stated that the named health professional did not select or identify practices to receive these educational meetings.

The named health professional was selected to speak for the reasons explained above. During interviews representatives were specifically asked if they had ever felt pressured to select the named health professional as a speaker; in all cases representatives replied that they did not.

Explanations about references in the CRM system were provided. Most related to the named health professional's availability to speak. Furthermore, the three entries in October and November 2015 referring to 'data added tools' and 'an audit tool' related to an Excel spreadsheet made available on request to health professionals to monitor patients' outcomes.

The named health professional correctly signed the authorisation line requiring a signature from a 'member of the meeting organising committee'. The 'approved by' line should have been signed by the representative approving payment for use of exhibition space but was signed by the named health professional in error. This form was then sent to the representative's line manager for approval who appeared not to have noticed this error during his/her review and approval of the meeting.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

The complaint raised concerns about the interactions of certain pharmaceutical companies, including Boehringer Ingelheim, and the training and consultancy company run by the named health professional. The complainant stated that the named health professional, a nurse, was employed on a contractual basis by a number of NHS organisations including the named city based CHO. Reference was made to his/her prescribing responsibility and alleged influence in a named CCG area and to the training and consultancy company services provided locally. The training and consultancy company offerings were said to range from practice audits, health professional mentoring and education to classroom based training workshops. More detailed allegations were made in relation to audits and workshops. The complainant alleged that the amount of money that industry had pumped into these courses was 'staggering' and could be perceived as an attempt to 'buy the business'. The complainant also generally referred to the Authority investigating the relationship between the named health professional and certain pharmaceutical companies. In this regard the Panel noted that it could only consider specific matters raised in the complaint.

The Panel noted that the complainant began by stating that he/she wished to complain about the conduct of the training and consultancy company, referred to grave concerns about it and the path which the complainant alleged had been taken by its owner, the named health professional, to extract financial support from the industry including highly coercive behaviour; in this regard the Panel noted that the Code applied solely to the conduct of pharmaceutical companies.

The Panel considered that the complaint was broader than the two matters identified by the case preparation manager, ie audits and specific workshops. The complainant had referred generally to training and support for health professionals delivered by the named health professional but paid for by the pharmaceutical industry. AstraZeneca had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner, the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

The Panel noted that the complainant had provided a website address for the training and consultancy company and this had been provided to all respondent companies. The website listed the named health professional as the Director and another health professional as the nurse liaison lead. The Panel noted that the named health professional

was contracted by the NHS to work at a number of surgeries in addition to his/her role at the named city based CHO.

The Panel noted that the complainant had raised concerns in relation to a number of pharmaceutical companies which were taken up with each company individually. Companies made differing submissions about the training and consultancy company and the role and status of the named health professional. Each case was considered on its merits.

In addition, the Panel noted that the case preparation manager had stated that matters would be considered in relation to the requirements of the Code applicable when the matters at issue occurred

In addition, the Panel noted the case preparation manager's advice that matters would generally be considered in relation to the requirements of the Code applicable when the matters at issue occurred. However, the Panel noted that AstraZeneca had sponsored a training and consultancy company meeting in October 2014. The Panel noted that there was a relevant difference between the 2014 and 2016 Codes in the supplementary information to Clause 2 in that the supplementary information to the 2016 Code gave 'unacceptable payments' as an example of a breach of Clause 2. This difference was potentially relevant to the matter at issue and thus all matters pertaining to the October 2014 meeting were ruled under the requirements of the 2014 Code.

The Panel noted that in relation to activities that occurred in 2015 in the particular circumstances of this case there were no significant differences between the relevant requirements of the 2015 and the current 2016 Code and thus these matters were considered under the 2016 Code.

The Panel noted that according to AstraZeneca it had sponsored only one meeting run by the training and consultancy company which was held in October 2014. The meeting about a particular condition had a 1 day educational agenda which began at 9.30am. The Panel was very concerned that the form authorising electronic payment to the training and consultancy company was signed as approved by the named health professional rather than, as required, by the representative. This was apparently not noted at the time by the representative and/or line manager responsible for overall review and approval of the meeting. However, the Panel noted that the complainant bore the burden of proof and considered that the complainant had not established on the balance of probabilities that either the provision of sponsorship or the level of sponsorship was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 18.6 was ruled. Noting this ruling the Panel also ruled no breach of Clauses 9.1 and 2. These rulings were made under the 2014 Code.

The Panel noted that AstraZeneca had engaged the named health professional 54 times between May 2014 and June 2016 to speak and twice to chair its lunchtime or evening promotional meetings. In addition, the named health professional had been engaged 5 times between May and November 2015 as a speaker on its Expert on Demand Programme.

The Panel noted that although AstraZeneca referred to the appointment of the named health professional as an individual the fee for service contracts showed that the fees were in fact paid to the training and consultancy company. The Panel therefore considered this matter under both Clauses 23 and 21.

The Panel noted that the SOP on External Interactions dated May 2012 stated at section 5 that, *inter alia*, the company would only engage health professional service providers where there was a legitimate need for their services, the relevant person was an appropriate candidate and the level of compensation did not have and did not create an impression that the company had undue influence on the individual. Written director approval was needed before contracting with a health professional service provider for any further employment over 20 engagements, or over a set amount, in a 12 month period. There was no evidence before the Panel to show that in relation to the 29 speaker meetings and 5 Expert on Demand engagements in 2016 such approval had been sought. The Panel noted the fair market value speaker fees table. According to the sales force compliance guide there had to be written justification for fees at the top end of the fair market value range and signatory approval for fees outside the fair market value range. The Panel noted the payment to the named health professional/ training and consultancy company for the 29 speaker meetings held in 2016 and most meetings in 2016. It appeared to the Panel that particularly for the meetings held at GP practices which comprised one presentation of an hour or less the monies paid exceeded the values in the fair market value table. The Panel noted that the SOP was dated May 2012 but it was nonetheless provided by the company as a current document. There was no evidence before the Panel that there had been written justification and/or signatory approval of the fees as stated in the relevant SOP.

The Panel noted AstraZeneca's submission that it had engaged the named health professional because of his/her experience, knowledge and availability, and as he/she was not an NHS employee he/she was available for daytime meetings as he/she was not subject to restrictions on speaking at industry-led promotional daytime meetings. The Panel noted that nonetheless he/she had also been engaged to speak at evening meetings.

The Panel noted that according to AstraZeneca its representatives did not feel pressurised to select the named health professional as a speaker and that he/she did not identify practices to receive these meetings. The Panel noted the high level of contact between representatives and the named health professional at various surgeries in addition to contact at the speaker meetings. The customer relations management (CRM) entries did not show whether such contacts were solicited or unsolicited. The CRM entries showed that on occasion such contacts included discussion of educational needs. The Panel noted AstraZeneca's submission that CRM

references to 'mapping out practices' and 'further surgeries to consider' referred to the named health professional's availability to speak rather than practice selection.

The Panel noted AstraZeneca's submission that it did not normally engage a speaker 56 times over 2 years within a relatively small geographical area. The named health professional had spoken more than once at a number of GP practices. The company stated that it first became aware of the high use of the named health professional on 13 July 2016 (ie before it was notified of this complaint) but did not state what had triggered this.

The Panel noted that paragraph 2 of the fee for service speaker contracts stated that the consultant confirmed that he/she did not interpret the engagement as an incentive or reward for past, present or future willingness to or as an inducement to, *inter alia*, prescribe or recommend AstraZeneca's product or to secure any improper advantage for the company. Paragraph 5 provided that the speaker acknowledged that he/she had been selected to provide the services because of his/her relevant expertise.

In relation to the speaker meetings whilst it had concerns about the company's governance of the activities and materials the Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional/the training and consultancy company was an inducement to prescribe as alleged. No breach of Clauses 21 and 23.1 was ruled.

In relation to the Expert on Demand Programme the Panel noted that this was a promotional programme whereby experts delivered 30 minute on line presentations via WebEx. The named health professional had delivered 5 such meetings in 2015 and had been paid the same amount for each. Section 2 of the fee for service contract for the Expert on Demand Programme, dated 28 January 2015 stated that the named health professional did not interpret this engagement as an incentive or reward or an inducement to, *inter alia*, recommend or prescribe any AstraZeneca product. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement was an inducement to prescribe. No breach of Clauses 21 and 23.1 was ruled.

The Panel noted its comments above regarding the fees paid to the named health professional/ the training and consultancy company. It also noted the number of speaker engagements and considered that when an individual/organisation was so engaged it was beholden upon the company to ensure that all aspects of the arrangements stood up to scrutiny and otherwise complied with the Code. Despite its frequent engagement of the named health professional over 2 years, AstraZeneca only became aware of the fact in July 2016, even though such frequent engagement was not in accordance with the company's policies and procedures. The impression created both externally and internally by such arrangements should be borne in mind. The Panel also noted the high number of representative contacts with the named health professional at various local practices. It did not appear that the company had exercised due diligence in its multiple engagements of the named health professional. Such engagements were not in accordance with the relevant SOPs. In this regard, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel, however, did not consider that the complainant had established a breach of Clause 2 and no breach of Clause 2 was ruled accordingly.

The Panel noted that AstraZeneca had also been asked to respond to the requirements of Clause 19.1 of the Code. There was no evidence before the Panel that AstraZeneca had engaged in any relevant activity. No breach of Clause 19.1 was thus ruled.

The Panel noted that AstraZeneca had provided details of monies paid to the named health professional in relation to training he/she received to become an Expert on Demand speaker. The Panel considered that this matter was outside the scope of the complaint and thus made no rulings upon it.

During its consideration of this case the Panel was concerned about the poor control exercised by AstraZeneca over certain activities. In relation to sponsorship of the exhibition stand meeting in October 2014 the Panel was extremely concerned that the representative and his/her line manager had failed to notice that the named health professional had signed the 'approved by' line and thereby approved payment of funds to himself/the training and consultancy company.

The Panel noted that AstraZeneca had identified improvements to its procedures but nonetheless requested that the company be advised of its concerns.

Complaint received **3 August 2016**

Case completed **3 January 2017**