

ANONYMOUS, NON CONTACTABLE v LILLY

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 Lilly. 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 Lilly 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.

The Panel noted Lilly's submission that it had sponsored 13 meetings run by the training and consultancy company. Eight of these meetings were for an exhibition stand at two day accredited training courses. The remaining five were for courses at local surgeries and hospitals. The Panel noted that for all 13 meetings the training and consultancy company and the city based CHO's therapy area team lead for specialist nurses and dieticians had full responsibility for the meetings' content and speakers, and for the accredited training courses, selection and registration of attendees from a named CCG. The Panel noted that sponsorship of the accredited training courses varied according to whether Lilly was one of two sponsors or the sole sponsor. In relation to the other 5 courses

run at surgeries and hospitals, the amounts paid in sponsorship again varied according to the duration of the meeting. The Panel noted that there had been 30 contacts between the local representatives and the named health professional between February 2015 and March 2016. No details were provided about the status of the contacts, nonetheless the overall number appeared high. According to Lilly during its internal investigation there was no report or indication that its representatives felt pressurised or obliged to offer support to the training and consultancy company or the named health professional. 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 for any of the meetings was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of the Code was ruled. High standards had been maintained and a further ruling of no breach of the Code was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that there was no evidence before the Panel that Lilly had engaged in any relevant activities alleged and the Panel ruled no breach of the Code.

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 pharmaceutical companies including Eli Lilly & Company Limited.

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, 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 Lilly, 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

Lilly submitted that it took any suggestions of improper conduct extremely seriously and immediately undertook an investigation which was now complete with relevant staff interviewed. Lilly was confident that it had acted appropriately and transparently in all interactions with the training and consultancy company and the named health professional. Lilly therefore refuted all allegations of improper conduct or Code breaches.

Clinical Audit

Lilly submitted that it had not engaged with the training and consultancy company or the named health professional for the purpose of any clinical audit. No clinical audits had been carried out by the training and consultancy company or the named health professional on behalf of Lilly nor had Lilly funded the training and consultancy company or the named health professional to support any clinical audits.

Training Workshop

Lilly submitted that it had sponsored certain meetings conducted by the training and consultancy company for the CCG in which the named health professional had prescribing responsibility. The Sponsoring Independent Meetings for Health Professionals standard operating procedure (SOP) applied to the review and approval of sponsorship of independent meetings. The corresponding form to be completed by field-based staff for approval of meeting sponsorship was also provided as was a copy of the Guidance for Independent Stand Meetings which was referred to in the above SOP. An email template sent to HCOs by Lilly customer meeting services confirming independent meeting sponsorship by Lilly was also provided.

Lilly submitted that during 2015 and 2016, it sponsored 13 meetings organised and run by the training and consultancy company. Lilly paid the training and consultancy company following the Sponsoring Independent Meeting procedure and using the appropriate form. Agenda for these meetings were provided.

Lilly submitted that it was approached by the training and consultancy company in 2015 to sponsor a number of meetings run by it for the CCG in which the named health professional had prescribing responsibility. Lilly was not obliged to sponsor the meetings and nor did it expect or receive any improper benefit for its sponsorship. The sponsorship of these meetings was open to all interested pharmaceutical companies including Lilly. The CCG covered a large area and had a patient population of approximately 39,000 and 62 GP practices. Lilly understood that the team lead for specialist nurses and specialist dieticians at city-based community healthcare organisation had worked with the training and consultancy company to develop a programme of meetings, including the accredited training to educate GPs and practice nurses across the CCG.

The training and consultancy company and the team lead developed the course content and managed all aspects of these meetings including securing sponsorship from pharmaceutical companies for the meetings.

The named health professional had been the point of contact at the training and consultancy company for Lilly when sponsoring these meetings, in addition to the team lead.

Lilly submitted that whilst it had sponsored independent meetings run by the training and consultancy company, it did not have any other commercial relationship and confirmed that all payments made to the training and consultancy company had been in relation to sponsorship of independent meetings organised by the training and consultancy company.

The named health professional confirmed to Lilly that the training and consultancy company was an independent training provider and did not receive any funding from the CCG in which he/she had prescribing responsibilities for its meetings.

Lilly submitted that it was not involved in any aspect of clinical audits carried out by the training and consultancy company and so could not provide any account of arrangements and it had made no associated payments. It was therefore also unable to provide any materials associated with such audit. Lilly confirmed that none of its representatives were involved in the training and consultancy company clinical audits and therefore Lilly was unable to provide any information of surgeries selected and how any subsequent uplift in sales were monitored. Lilly was also unable to provide any information on how medicines were chosen in such audits.

Lilly provided details of the 13 meetings run by the training and consultancy company which it sponsored during 2015 and 2016.

The training and consultancy company and the team lead were responsible for all arrangements of the meetings including the selection and registration of the CCG attendees. The training and consultancy company confirmed that these meetings had 18-24 participants and 4-6 speakers on the programme. The training and consultancy company and the team lead were fully responsible for meeting content and any associated speakers. The training and consultancy company provided a separate room for its sponsors to exhibit and did not permit sponsors to participate in the meeting programme. The training courses were accredited by the RCGP and the RCN and certified by the CPD Certification Service.

The training and consultancy company and the CHO team lead were also fully responsible for the content and any associated speakers for the remaining five the training and consultancy company meetings sponsored by Lilly. The training and consultancy company provided a separate room for its sponsors to exhibit and did not permit sponsors to participate in the meeting programme. Further details of these meetings were provided.

Lilly submitted that it had not supported any other courses in the relevant geographical area but had sponsored a further 11 independent meetings organised by other providers/organisations for health professionals in certain CCGs.

In summary, Lilly submitted that it had appropriately sponsored meetings organised and run by the training and consultancy company and the team lead for the CCG which provided education for health professionals in an effort to improve the care delivered to patients in the CCG. The meetings had clear educational content; were held in appropriate venues conducive to the main purpose of the meeting and provided modest subsistence to attendees who were health professionals within the CCG.

Accordingly, Lilly refuted any breach of Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 or 23.1 with regard to the clinical audit and with regard to the accredited training workshops delivered in partnership with the CCG.

Lilly submitted that it took the matter of its staff being able to 'speak up' very seriously and had initiated an internal investigation to establish if any employee felt he/she could not speak up and report concerns about Lilly's business.

Lilly understood and fully respected the Code and strove to ensure that all activities always complied with the Code.

In response to a request for further information Lilly stated that a senior director who was not part of the UK sales and marketing affiliate had conducted an internal investigation into the company's relationship with the training and consultancy company, to establish if any Lilly employee felt he/she could not speak up and report concerns about Lilly's business. All employees from the relevant geography were interviewed and it was concluded:

- There was no evidence that Lilly had been involved in or funded clinical audits, nurse-led reviews or clinics to assess patients with a particular condition in a named area
- There was also no evidence that Lilly had indirectly paid for the training and consultancy company to conduct clinical audits
- That the training and consultancy company was selected by the CCG in which the named health professional had prescribing responsibility to facilitate CCG educational meetings. The CCG asked Lilly and other sponsors to support the CCG programme by sponsoring the training and consultancy company. The agenda for the meetings was not determined by or influenced in any way by Lilly.

No Lilly employee felt he/she could not speak up and report concerns about Lilly's business.

In response to specific questions raised Lilly responded as follows:

Clinical audits

Lilly confirmed that it had not directly funded a practice or group of practices for it to carry out

an audit/review independently of Lilly. Lilly had not directly or indirectly paid the training and consultancy company to conduct clinical audits. Lilly had not funded any activity provided by the training and consultancy company which might be described as a nurse-led review, a clinic to assess diabetics, or any similar activity.

Meetings

In response to a request to explain the process by which Lilly decided to work with the training and consultancy company Lilly explained that the training and consultancy company was selected by the CCG in which the named health professional had prescribing responsibility to facilitate its education meetings. The CCG asked Lilly and other pharmaceutical companies to sponsor these independent meetings, payment was to be made to the training and consultancy company which would run the meetings on behalf of the CCG. Lilly understood that the team lead for specialist nurses and dieticians at the CHO had worked with the training and consultancy company to develop the programme of meetings, including the accredited training courses, the aims of which were to educate GPs and practice nurses across the CCG.

Lilly did not know if the training and consultancy company was the only regional provider of such services.

Lilly provided details of the sponsorship of each of the 13 meetings including monies paid. Lilly had confirmed to the training and consultancy company and/or the team lead for each meeting that the sponsorship was of an independent stand meeting and was for Lilly to have exhibition/stand space.

The sponsorship of these independent meetings was such that the CCG and the training and consultancy company remained in full control of the agenda, course content, speaker selection and their payment, and registration of delegates.

In response to a question about what factors Lilly took into account in deciding whether the amount paid was reasonable Lilly explained that the Lilly representatives and manager would have known about and followed the guidance in the Lilly job aid 'Guidance for Independent Stand Meetings' (copy provided) when they reviewed and decided whether the sponsorship amount was reasonable. They would have considered the Lilly exhibition/stand space and opportunity in light of the probable hire costs of the venue; the modest subsistence, and the speakers' honoraria required to run such meetings.

In response to a question about how the meetings were approved the Lilly representative received a verbal request to sponsor the meetings from the training and consultancy company/the CCG. The representative completed the Independent Stand Meeting Sponsorship form and submitted it to his/her line manager for approval. The line manager then approved the arrangements for the sponsorship of the meeting. These details were submitted to the Lilly Customer Meeting Services Team (LCMS) which

confirmed the sponsorship details with the training and consultancy company/the CCG.

For each meeting Lilly supplied the completed Independent Stand Meeting Sponsorship form, the agenda provided to Lilly, the email of the manager's approval of the meeting, the email sent to the training and consultancy company/the CCG by LCMS confirming the details of the sponsorship and confirmation that the meeting took place and payment being made.

Lilly provided details of contacts entered in the CRM between Lilly representatives and the named health professional for 2015 and 2016.

When asked to comment on the allegation that sponsorship of these meetings could be seen as an attempt to buy business Lilly stated that the sponsorship was not related to the sales of Lilly products either past or anticipated in future. Lilly had appropriately sponsored independent educational meetings developed by team lead and the training and consultancy company that were accredited by the RCGP and the RCN. Lilly was not obliged to sponsor the meetings nor did it expect or receive any improper benefit for its sponsorship. The allegation that such support by Lilly 'could be seen as an attempt to buy business' was unfounded and wrong.

Lilly confirmed that during the thorough internal investigation there was no report or indication that any representative felt pressurised or obliged to support the training and consultancy company and/or the named health professional.

In relation to two day training courses in April and July 2016 which were also sponsored by Boehringer Ingelheim, Lilly confirmed that these were not Boehringer Ingelheim/Lilly Alliance activities. Each company sponsored them separately.

Lilly stated that it understood and fully respected the Code and strove to ensure that all activities were in full in adherence with the Code at all times.

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 Lilly, 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. Lilly 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 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 there were no significant relevant differences between the requirements of the 2016 Code and the requirements of the 2015 Code. The rulings were therefore made under the requirements of the 2016 Code.

The Panel noted Lilly's submission that it had sponsored 13 meetings run by the training and consultancy company between June 2015 and July 2016. Eight of these meetings were for an exhibition stand at two-day accredited training courses. The remaining five were for courses at local surgeries and hospitals and were devised and run by the training and consultancy company. The Panel noted that for all 13 meetings the training and consultancy company and the CHO team lead for specialist nurses and dieticians had full responsibility for the meetings' content and speakers, and for the accredited training courses, selection and registration of the CCG staff. The Panel noted that according to the website for the training and consultancy company, the CHO team lead for specialist nurses also had a role at the training and consultancy company. The Panel noted that the meetings which all had a detailed educational agenda were accredited by the RCN and the RCGP. The Panel noted that sponsorship of these courses varied according to whether Lilly was one of two sponsors or whether it was the sole sponsor. In relation to the other 5 courses run at surgeries and hospitals, amounts paid in sponsorship again varied according to the duration of the meeting. The Panel noted that one of the agendas/invitations for the remaining 5 meetings gave little detail about its educational content. The Panel noted that there had been 30 contacts between the local representatives and the named health professional between February 2015 and March 2016. No details were provided about the status of the contacts, nonetheless the overall number appeared high. According to Lilly during its internal investigation there was no report or indication that its representatives felt pressurised or obliged to offer support to the training and consultancy company or the named health professional. 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 for any of the meetings was an inducement to prescribe or otherwise inappropriate in relation to the matters alleged. No breach of Clauses 18.1 and 19.2 was ruled. High standards had been maintained; no breach of Clause 9.1 was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that Lilly had also been asked to respond to the requirements of Clauses 19.1, 21 and 23.1 of the 2016 Code. There was no evidence before the Panel that Lilly had engaged in any relevant activities and the Panel ruled no breach of Clauses 19.1, 21 and 23.1 accordingly.

Complaint received	3 August 2016
Case completed	19 December 2016