CASE AUTH/2220/3/09

ANONYMOUS v LILLY

Conduct of representative

An anonymous and non contactable complainant who described himself as a member of a practice based prescribing commissioning consortia (PBC) in a local primary care trust (PCT) complained an Eli Lilly representative had set up a six day diabetes training course for the complainant's group without the permission of the local diabetes team. He had the trainers discuss mostly his company's products.

The detailed responses from Lilly are given below.

The Panel noted that, according to Lilly, prior permission for the course was obtained from the local PCT. No breach of the Code was ruled.

The Panel noted that the Type 2 Diabetes Foundation Course was five separate days of education aimed at primary care and produced by a university. The course was sponsored by Lilly which met room rental and speaker costs. The course covered various aspects of diabetes diagnosis, lifestyle issues, treatment and complications.

The Panel noted that references to Lilly's or other companies' medicines appeared in some of the material provided. The Panel noted that some of the slide sets used came from clearly identified third party sources. Some of these slides referred to therapies either by brand name or non-proprietary name and it was not surprising, given Lilly's commercial interest in the area, that its medicines were named along with those from other companies. Similarly, a large proportion of slides which were not accredited to any organization or individual, also referred to Lilly's products. The Panel did not know if Lilly had influenced the content of these slides in any way.

Day three of the course, however, featured a presentation from a member of Lilly's staff using the company's own slides 'Initiating and Managing Injectable Therapy in [Type 2 Diabetes Mellitus]. An Electronic Pathway'. The title slide clearly stated 'Sponsored by Eli Lilly & Company Limited' and each slide featured the company logo in the bottom right hand corner. Given that this was thus a promotional presentation on behalf of Lilly, the company had to be responsible for it under the Code. The presentation promoted Humalog (insulin lispro), Humalin (insulin) and Byetta (exenatide), prescribing information for which was included in the material. The Panel noted that on the agenda although the presenter was named the fact that she was employed by Lilly was not; the presentation thus appeared to be an integral part of the university course which was not so. The Panel did not know what delegates were told about the provenance and status of the material and presentation. The Panel queried whether the presentation had been approved by the university for inclusion as part of its course. The Panel noted Lilly's submission that its presentation supplemented the university course.

The Panel noted the complainant's allegation that the trainers mostly discussed Lilly's products. The Panel noted that the audience comprised prescribers. The Panel considered, on balance, that the inclusion of the Lilly promotional presentation and material as an apparently integral part of an otherwise well-recognized independent educational course was inappropriate such that the representative had not maintained high standards. A breach of the Code was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2.

The complainant alleged that the representative had brought in a diabetes specialist nurse from elsewhere to some practices in his group and had the nurse see patients and change their medicine to Lilly's product Byetta. At one particular practice the patient was then seen at the hospital following complications.

The representative brought in other people to run audits and then pushed his medicines for the people as 'not controlled'. He had done this in nearly all of the GP practices in the group.

The Panel noted that the service implemented by a third party reviewed type 2 diabetics who were sub-optimally controlled on maximally tolerated doses of more than one oral therapy in line with National Institute for Health and Clinical Excellence (NICE)/local guidelines and/or practice agreed protocols. A service booklet described the service and featured a treatment flowchart reproduced from NICE Guideline 2008. The third treatment stage ie when oral therapy with metformin and a sulphonylurea had failed (HbA1c ≥7.5% or as individually agreed) was stated to be 'Add thiazolidinedione or insulin with active dose titration' but adjoining this was a highlighted box which read 'Exenatide may be considered here when body weight is a special problem and recommendations in the guideline are met'. The Panel noted that whilst this was an accurate reproduction of the NICE guidance it queried whether the reference to exenatide (Byetta) was appropriate in a booklet introducing a non promotional service. The flowchart otherwise referred to classes of product.

The representative introduced the service at an

initial meeting with the GP and completed the practice authorization form. The practice then contacted the third party which thereafter ran the service. The authorization form referred to the practice confirming both the treatment protocol and the nurse implementation of any actions that the practice requested.

One of the elements of the service was a third party nurse-facilitated 3 hour education and training workshop on the management of type 2 diabetes tailored to practice requirements. The workshop incorporated a case note review on patients suboptimally controlled on the maximally tolerated dose of more than one oral therapy in line with NICE guidelines. The practice staff thereafter conducted review clinics with the nurse in attendance.

The Panel noted that according to its summary of product characteristics (SPC) Byetta was indicated for treatment of type 2 diabetes in combination with metformin and/or sulphonylureas in patients who had not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

The Panel noted that the NICE Guideline on the management of type 2 diabetes stated that exenatide was not recommended for routine use in type 2 diabetes. It could be considered as an option only if the patient satisfied each of four requirements relating to body mass index; specific problems of psychological biochemical or physical nature arising from high body weight; inadequate glucose control with conventional oral agents after a trial of metformin and sulphonylurea; and other high cost medication, such as thiazolidinedione or insulin injection therapy would otherwise be started.

The training materials discussed the role of the representative, it was made clear that the service should be introduced briefly during a promotional call. A detailed discussion could only take place during a non promotional call which should take place at least 24 hours later. The requirements of the Code and its relevant supplementary information were discussed. One document referred to the representative providing administrative support. The material did not make it abundantly clear that the representative should be mindful of the requirements of the Code during the implementation of the audit.

The Panel noted that the material referred to exenatide and/or its licensed indication. The Panel noted that the practice confirmed the treatment protocol and authorized the activities of the nurse. The Panel noted that there was no evidence before it that the audit was inappropriate or that patients had been inappropriately switched to exenatide as alleged. Nor was there any evidence that the representative had pushed his medicines for uncontrolled patients as alleged. The Panel noted that the complainant was anonymous and non contactable. No additional material had been submitted. The complaint had the burden of proving their complaint on the balance of probabilities. The Panel ruled no breach of the Code including Clause 2.

The complainant alleged that the representative pushed GPs and practice nurses to prescribe insulin when not comfortable to do so (his company's of course) and not refer to specialists in the community. The reason was the specialists didn't use his.

The Panel considered that the complainant had not established that the representative had inappropriately promoted products as alleged. No breach of the Code were ruled.

The complainant alleged that the representative had funded the writing of the local PBC business plan and the diabetes protocol; this was unethical. The representative had acted via the PBC lead whom he had seen at least 15-20 times and taken out for many meals.

The Panel noted Lilly's submission that neither it nor the representative had funded the writing of the PBC business plan or diabetes protocol, and no breach was ruled.

The Panel was very concerned that Lilly's call record system did not detail whether a call was at the request of a health professional. It was thus difficult to see how Lilly could demonstrate compliance with the Code. Although Lilly had provided a copy of a field force presentation this only demonstrated that relevant training had been provided; it did not establish whether the number of calls upon a specific health professional complied with the Code.

The Panel noted Lilly's submission that the vast majority of the 17 calls in 2008 were solicited and was confident that its representative had not breached the Code. Records submitted by Lilly showed that the representative had face-to-face contact with the PBC lead seven times over the course of the nine weeks. Three of the meetings took place in the private rooms of restaurants. All but one of the meetings appeared to have been recorded as a 'group sell'. The remaining meeting was a 1:1 meeting during which the representative detailed the 'entire portfolio of insulins and Byetta'. The Panel was concerned about the arrangements and noted that the impression created by the arrangement of any meeting must be kept in mind. Nonetheless the burden of proof fell on the complainant. Lilly had submitted that the vast majority of calls were solicited. The Panel did not consider that it had been established on the balance of probabilities, that the calls by the representative on the PBC lead were inconsistent with the requirements of the Code and no breach was ruled.

The complainant alleged that the representative

had an accomplice, a local hospital diabetes consultant. This doctor always used Lilly products, did many talks for the representative who the complainant alleged remunerated him well. The complainant had seen them together at least 10 times in the last 6 months. The complainant was sure in the diabetes consultants area, if the Authority looked at Lilly insulin sales, there would be a huge increase. How could this be allowed to happen?

The Panel noted its critical comments about Lilly's call record system above and considered they were relevant here. In the last 6 months the consultant had presented at 11 Lilly sponsored meetings and had 17 1:1 meetings with the representative. The Panel noted Lilly's submission that its internal policies required 1:1 calls by the representatives to arrange the meeting and sign anticorruption and due diligence forms. The Panel queried whether a 1:1 meeting was indeed necessary to sign an anticorruption form on each occasion when the same speaker spoke at a series of company meetings in the same therapeutic area and was no doubt already familiar with the company's policies and procedures. Irrespective of the company's internal policy it was very difficult to see how 17 1:1 meetings in a six month period could meet the requirements of the Code.

Unlike its response above Lilly did not quantify the number of calls solicited by the consultant. The Panel considered the arrangements unacceptable. The Panel considered that the totality of the evidence was such that on the balance of probabilities the number of meetings with the hospital consultant was inconsistent with the Code and a breach of the Code was ruled. The Panel did not consider that there was evidence to establish that the meetings amounted to an inducement to prescribe Lilly's products or that the honoraria were otherwise unacceptable as alleged. No breaches of the Code were ruled.

The complainant alleged that the representative pushed the local GPs to refer to the diabetes consultant at a local hospital, because he used Lilly products, and not to its local specialist team for insulins and diabetes management.

The Panel considered that there was no evidence that the representative had inappropriately pushed the complainant's GPs to refer patients to the hospital consultant as alleged. No breach of the Code was ruled.

The complainant alleged that the representative constantly criticised its local diabetes service, the members of its secondary care team and their competency in doing their jobs.

The Panel considered that there was no evidence that the representative had behaved as alleged. No breaches of the Code were ruled.

The complainant alleged that the representative had on many occasions taken GPs from the complainant's group out for a meal with no education – just a free meal.

The Panel noted that each of the meetings was arranged by the PBC and sponsored by Lilly. The company was unable to provide copies of the agendas or invitations. The representative gave a promotional talk at each meeting. Lilly should be able to demonstrate that the meetings were appropriate to sponsor and that the arrangements complied with the Code including the invitation and agenda. It was difficult to see how such meetings could be approved as submitted by Lilly without sight of the agenda or invitation. The Panel was very concerned about the apparent lack of control. There was, however, no evidence to support the allegation that the meetings comprised a free meal with no education. No breaches of the Code were ruled.

The complainant alleged that the representative constantly pushed many of the local complainant's GPs to switch their patients from a competitor insulin to a Lilly insulin.

The Panel again noted that the complainant had not established that the representative had inappropriately promoted his products as alleged. No breach of the Code was ruled.

An anonymous and non contactable complainant who described himself as a member of a practice based prescribing commissioning consortia (PBC) in a primary care trust (PCT) complained about the conduct of a representative from Lilly.

When writing to Lilly, the Authority asked it to respnd in relation to Clauses 2, 8.2, 15.2, 15.3, 18.1, 18.4 and 19.1 of the Code.

1 Diabetes training course

COMPLAINT

The complainant alleged that the representative had set up a six day diabetes training course for the complainant's group without the permission of the local diabetes team. He had the trainers discuss mostly his company's products.

RESPONSE

Lilly explained that the representative was approached by the PBC lead and asked if he/Lilly could help with diabetes education within the PBC. As a consequence, the representative contacted another doctor, to run the university course which was proposed, with assistance from a consultant in diabetes.

It subsequently transpired, before the commencement of the course that although local

approval was to be sought, permission to run the course had not been obtained. The course was therefore put on hold until approval was obtained.

The six day Type 2 Diabetes Foundation Course was subsequently accredited by the Royal College of Nursing (RCN) and was run between 20 October 2007 and 14 June 2008 – by a university accredited trainer and diabetes education facilitator (nurse consultant), the local professor of diabetes and the local diabetes consultant. Lilly provided copies of course documentation. The course covered a wide range of diabetes-related topics. The slides used were checked and approved by one of the company's clinical research physicians (CRPs). The agendas and slide-sets used did not refer to Lilly's (or any other company's) medicines, since the course was solely educational, not promotional. Day Six was set aside for end of course exams.

The agenda for day one stated that 'This meeting has been sponsored by an Educational Grant provided by Lilly', which was not so; the meeting was sponsored by Lilly and subsequent agendas stated 'This Educational Event is sponsored by Lilly'. Lilly explained that the 6 day course, the Type 2 Diabetes Foundation Course, was facilitated by a university accredited trainer (nurse consultant). On completion of the course, each delegate received a certificate, an example of which was provided.

With regard to the slides sets used, these were all approved in advance of the course by one of Lilly's CRPs. It was not possible to determine which of the slides was used with each part of the agenda, since, being a training course, the nurse consultant as the educational facilitator, would have moved between the available slides, dependent on the discussion. The additional Lilly material was presented by, a medical liaison officer and a member of Lilly's medical department. The Lilly materials were clearly branded as such and did not form part of the university accredited course facilitated by the nurse consultant, but supplemented it.

PANEL RULING

The Panel noted that on receipt of Lilly's response it had become apparent that the five day course at issue had been held on various dates between 20 October 2007 and June 2008 and thus the requirements of the 2006 Code applied. However the clauses cited by the Authority were the same in the 2006 Code as in the 2008 Code. The case was thus considered under the 2008 Code.

The Panel noted that the complainant was anonymous and non contactable. The complainant had not provided any additional material to support their allegations. The complainant had the burden of proving their complaint on the balance of probabilities.

The complainant had alleged that the course was run without the permission of the local diabetes team. The Panel noted that, according to Lilly, prior permission for the course was obtained from the local PCT. No breach of Clause 15.2 was ruled on this point.

The Panel noted that the Type 2 Diabetes Foundation Course was five separate days of education aimed at primary care and produced by a university. The course was sponsored by Lilly which met room rental and speaker costs. The course covered various aspects of diabetes diagnosis, lifestyle issues, treatment and complications. The Panel noted that it was possible for a company to sponsor material or an activity produced and provided by a third party which mentioned its own products and not be liable under the Code, but only if, *inter alia*, there had been a strictly arm's length arrangement between the parties. In practical terms the arrangements must be such that there could be no possibility that the pharmaceutical company had been able to exert any influence or control over the final content and provision of the material or activity.

The Panel noted that contrary to Lilly's submission that the slide sets used did not refer to Lilly's or other companies' medicines such references did appear in some of the material provided. The Panel noted that some of the slide sets used came from clearly identified third party sources. Some of these slides referred to therapies either by brand name or non-proprietary name and it was not surprising, given Lilly's commercial interest in the area, that its medicines were named along with those from other companies. Similarly, a large proportion of slides which were not accredited to any organization or individual, also contained references to Lilly's products. The Panel did not know if Lilly had influenced the content of these slides in any way.

Day three of the course, however, featured a one and a half hour presentation from a member of Lilly's staff using the company's own slides 'Initiating and Managing Injectable Therapy in [Type 2 Diabetes Mellitus]. An Electronic Pathway' (ref DBT148 June 2008). The title slide clearly stated 'Sponsored by Eli Lilly & Company Limited' and each slide featured the company logo in the bottom right hand corner. Given that this was thus a promotional presentation on behalf of Lilly, the company had to be responsible for it under the Code. The presentation promoted Humalog (insulin lispro), Humalin (insulin) and Byetta (exenatide), prescribing information for which was included in the material. The Panel noted that on the agenda although the presenter was named the fact that she was employed by Lilly was not; the presentation thus appeared to be an integral part of the university course which was not so. The Panel did not know what delegates were told about the provenance and status of the material and presentation. The Panel queried whether the presentation had been approved by the university for inclusion as part of its course. The Panel noted Lilly's submission that its presentation supplemented the university course.

The Panel noted the complainant's allegation that the trainers mostly discussed Lilly's products. The Panel noted that the audience comprised prescribers. The Panel considered, on balance, that the inclusion of the Lilly promotional presentation and material as an apparently integral part of an otherwise well-recognized independent educational course was inappropriate such that the representative had not maintained high standards. A breach of Clause 15.2 was ruled.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 and no breach of that Clause was ruled.

2 Diabetes specialist nurse and audit

COMPLAINT

The complainant alleged that the representative had brought in a diabetes specialist nurse from elsewhere to some practices in his group and had the nurse see patients and change their medicine to Lilly's product Byetta. At one particular practice the patient was then seen at the hospital following complications.

The representative brought in other people to run audits and then pushed his medicines for the people as 'not controlled'. He had done this in nearly all of the GP practices in the group.

RESPONSE

Lilly explained that it offered GPs a service, called the Enhanced Management of Type 2 Diabetes (EMD), in accordance with the provisions of the Code, including Clauses 18.1 and 18.4. It was intended to assist GP practices to implement the National Institute for health and Clinical Excellence (NICE)/local guidelines and/or practice protocols by reviewing type 2 diabetics who were sub-optimally controlled on maximally tolerated doses of more than one oral therapy. The service was provided via a third party which supplied IT and nurse resources across the UK for the appropriate identification and review of patients. The service was a therapy review, not switch, service: the representative had confirmed his understanding that this was how the EMD has worked; accordingly there was no question of the representative or 'pushing' Lilly medicines as alleged.

Since this service was unconnected with the promotion of any medicine, there was no obligation on a practice to participate unless practice staff wished to do so.

The programme worked by the practice being offered the service and it being explained to them. The nurse provided by the third party visited the practice and, working with practice staff, ran an educational and training workshop for them on the management of type 2 diabetes. The workshop was tailored to meet the individual practices' requirements: the 'Miquest' audit tool performed a search of all diabetic patients in the practice regardless of their current management. A case note review was conducted to identify patients with sub-optimally controlled diabetes, as described above: the practice determined the type of patients that it was most interested in reviewing; whilst those failing on oral therapies were one group, it might choose others. As with all the elements of this service, this decision was entirely in the hands of the participating practice and was documented as such in the practice authorisation form (a copy of which was provided). The practice staff then determined which patients to invite into the clinic, and conducted the therapy reviews, supported by the nurse advisor. Although the third party nurse advisor might offer support, it was the practice staff who decided on and initiated treatment, or made changes.

This service was offered to the PBC lead, and the service was run in ten local practices.

In response to a request for further information, Lilly provided copies of the representatives' training materials.

Accordingly, Lilly denied the allegations.

PANEL RULING

The Panel noted that medical and educational goods and services had to enhance patient care, or benefit the NHS and maintain patient care. With regard to therapy review services the supplementary information to Clause 18.4 provided helpful guidance. A therapeutic review which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. The results of such clinical assessments might require, amongst other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices including non medicinal choices and should not be limited to the medicines of the sponsoring pharmaceutical company. The arrangements for therapeutic review must enhance patient care, or benefit the NHS and maintain patient care. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual's treatment must be documented with evidence that it was made on rational grounds. The supplementary information also stated that sponsored health professionals should not be involved in the promotion of specific products. Nurses were required to comply with the Nursing and Midwifery Council Code of Professional Conduct which required that registration status was not used in the promotion of medicines.

The Panel noted that the service implemented by the third party reviewed type 2 diabetics who were sub-optimally controlled on maximally tolerated doses of more than one oral therapy in line with NICE/local guidelines and/or practice agreed protocols. A service booklet described the service and featured a treatment flowchart reproduced from NICE Guideline 2008. The third treatment stage ie when oral therapy with metformin and a sulphonylurea had failed (HbA1c ≥7.5% or as individually agreed) was stated to be 'Add thiazolidinedione or insulin with active dose titration' but adjoining this was a highlighted box which read 'Exenatide may be considered here when body weight is a special problem and recommendations in the guideline are met'. The Panel noted that whilst this was an accurate reproduction of the NICE guidance it queried whether the reference to exenatide (Byetta) was appropriate in a booklet introducing a non promotional service. The flowchart otherwise referred to classes of product. Clause 18.4 stated that medical and educational goods and services must not bear the name of any medicine. The supplementary information to that clause made it clear that this requirement did not apply when the goods consisted of independently produced textbooks or journals which included as part of their texts the names of medicines.

The representative introduced the service at an initial meeting with the GP and completed the practice authorization form. The practice then contacted the third party which thereafter ran the service. The authorization form referred to the practice confirming both the treatment protocol and the nurse implementation of any actions that the practice requested.

One of the elements of the service was a nurse-facilitated 3 hour education and training workshop on the management of type 2 diabetes run by the third party and tailored to practice requirements. The workshop incorporated a case note review on patients suboptimally controlled on the maximally tolerated dose of more than one oral therapy in line with NICE guidelines. The practice staff thereafter conducted review clinics with the nurse in attendance.

The Panel noted that according to its summary of product characteristics (SPC) Byetta was indicated for treatment of type 2 diabetes in combination with metformin and/or sulphonylureas in patients who had not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

The Panel noted that Section 1.6.3 of the NICE Guideline 66 on the management of type 2 diabetes stated that exenatide was not recommended for routine use in type 2 diabetes. It could be considered as an option only if the patient satisfied each of four requirements relating to body mass index; specific problems of psychological biochemical or physical nature arising from high body weight; inadequate glucose control with conventional oral agents after a trial of metformin and sulphonylurea; and other high cost medication, such as thiazolidinedione or insulin injection therapy would otherwise be started.

The training materials discussed the role of the representative, it was made clear that the service should be introduced briefly during a promotional call. A detailed discussion could only take place during a non promotional call which should take place at least 24 hours later. The requirements of Clause18.4 and its relevant supplementary information were discussed. One document referred to the representative providing administrative support. The material did not make it abundantly clear that the representative should be mindful of the requirements of the Code during the implementation of the audit.

The Panel noted that the material referred to exenatide and/or its licensed indication. The Panel noted that the practice confirmed the treatment protocol and authorized the activities of the nurse. The Panel noted that there was no evidence before it that the audit was inappropriate or that patients had been inappropriately switched to exenatide as alleged. Nor was there any evidence that the representative had pushed his medicines for uncontrolled patients as alleged. The Panel noted that the complainant was anonymous and non contactable and noted its comments at point 1 above about the burden of proof. The Panel ruled no breach of Clauses 18.1 and 18.4. The Panel consequently ruled no breach of Clause 2.

3 Conduct of the representative

COMPLAINT

The complainant alleged that the representative pushed GPs and practice nurses to prescribe insulin (Lilly's of course) even when not comfortable to do so and not to refer to specialists in the community because the specialists didn't use his medicines.

RESPONSE

Lilly explained that health professionals with adequate knowledge and training might prescribe a range of medicines according to local guidelines and formularies. Lilly understood that local GPs in this area might only initiate insulin with local PCT approval. Such GPs apparently acquired accreditation by attendance on the 'Insulins for Life' programme run by a diabetes consultant at a local hospital.

If a GP was accredited to prescribe insulins, then the representative might appropriately call on this GP to promote Lilly products, and using only materials certified in accordance with the Code. Lilly could provide copies of representatives' promotional materials if required.

Lilly submitted that the representative did not seek to hinder internal referral processes or pressurise staff into prescribing Lilly medicines when they were not comfortable to do so.

Lilly also referred to its response at point 6, below.

Accordingly, Lilly denied this allegation.

PANEL RULING

The Panel noted that the representative's primary role was to promote and inform health professionals about Lilly products. Such activity had to comply with the Code. The complainant had not established that the representative had inappropriately promoted his products as alleged. No breach of Clause 15.2 was ruled.

4 Funding of business plan and protocol

COMPLAINT

The complainant alleged that the representative had funded the writing of the local PBC business plan via the PBC lead. The representative had seen the PBC lead on at least 15-20 occasions and taken him out for many meals. He had funded the writing of the diabetes protocol, which the complainant alleged was totally unethical.

RESPONSE

Lilly submitted that neither the representative personally, nor the company, funded the writing of the PBC business plan or diabetes protocol. Accordingly, Lilly was unable to provide a copy of the protocol. There was no evidence of any other funding from Lilly for this activity via its Grants and Donations Committee, which administered grants and donations in response to unsolicited requests.

In 2008, the representative saw the PBC lead 17 times in 1:1 calls, the vast majority of which were at his request. These were not only promotional calls, but calls to help organise and run the six day training course, referred to at point 1, above. Unfortunately however, Lilly's call record system did not detail whether a call was at the request of the health professional or the company, so Lilly was unable to give the precise details in this regard. Lilly was however confident that the representative had not breached the requirements of Clause 15, including those of Clause 15.4.

So far in 2009 the representative had had one 1:1 call with the PBC lead at the surgery to promote Lilly medicines. Additionally, there had been 5 group sell meetings with members of this PBC, three of which had been at restaurants and two at the surgery.

Accordingly, Lilly denied the allegation.

In response to a request for further information about its call record system and whether such data was recorded in any other format to demonstrate compliance with Clause 15.4, Lilly stated that, as might be seen from the representatives' materials provided in relation to point 2 above, all of its representatives were trained on the Code and its internal SOPs. The requirements of Clause 15.4 ('Frequency and manner of calls on doctors and other prescribers') were specifically addressed as part of that training. Such data was not otherwise presently recorded in the call record system.

PANEL RULING

The Panel noted Lilly's submission that neither it nor the representative had funded the writing of the PBC business plan or diabetes protocol. It was unclear whether the diabetes plan had been discussed at any of the six group meetings held with members of the PBC. The Panel ruled no breach of Clauses 15.2 and 18.1 of the Code on this point.

The Panel noted that the allegation about the number of calls upon the PBC lead concerned Clause 15.4 of the Code. Whilst Lilly had not been asked to address this clause, it had, nonetheless, cited Clause 15.4 and responded in relation to its requirements. The Panel thus decided to rule under this clause.

The supplementary information to Clause 15.4 provided that the number of calls on, *inter alia*, a doctor by a representative each year should not normally exceed three on average, excluding attendance at group meetings, a visit requested by a doctor or call to respond to a specific enquiry or a visit to follow up a report of an adverse reaction. The Panel noted Lilly's account of the number of visits. The Panel was very concerned that Lilly's call record system did not detail whether a call was at the request of a health professional. It was thus difficult to see how Lilly could demonstrate compliance with Clause 15.4 of the Code. Lilly had explained that such compliance was demonstrated by reference to its representatives' training materials. That was not so. Lilly had provided a copy of a presentation 'The ABPI Code of Practice. Focus on Field Activities' (ref DBT 188) which discussed at slide 21 the requirements of Clause 15.4. Whilst such material demonstrated that relevant training had been provided it did not establish whether the number of calls upon a specific health professional complied with Clause 15.4.

The Panel noted Lilly's submission that the vast majority of the 17 calls in 2008 were solicited and was confident that its representative had not breached Clause 15.4 of the Code. Records submitted by Lilly showed that the representative had face-to-face contact with the PBC lead seven times over the course of the nine weeks. Three of

the meetings took place in the private rooms of restaurants. All but one of the meetings appeared to have been recorded as a 'group sell'. The remaining meeting was a 1:1 meeting during which the representative detailed the 'entire portfolio of insulins and Byetta'. The Panel was concerned about the arrangements and noted that the impression created by the arrangement of any meeting must be kept in mind. Nonetheless the burden of proof fell on the complainant. Lilly had submitted that the vast majority of calls were solicited. The Panel did not consider that it had been established on the balance of probabilities, that the calls by the representative on the PBC lead were inconsistent with the requirements of Clause 15.4 and its supplementary information. No breach of Clause 15.4 was thus ruled.

5 Meetings with a hospital consultant

COMPLAINT

The complainant alleged that the representative had an accomplice, a consultant in diabetes at a local hospital. This doctor always used Lilly products, did many talks for the representative who, the complainant alleged, remunerated him well. The complainant stated that the Authority would need to investigate how many times the representative had seen him. The complainant had seen them together on at least 10 occasions in the last 6 months. The complainant was sure in the diabetes consultant's area there would be a huge increase in the sales of Lilly's insulins. How could this be allowed to happen?

RESPONSE

Lilly stated that the diabetes consultant was, and had been, a speaker for Lilly, and also often asked the representative to visit. The consultant had presented at eleven Lilly sponsored meetings in the last 6 months and the representative had visited the consultant for 1:1 calls on 17 occasions during this time: in order to comply with Lilly's company policies and procedures, arrangement of a speaker meeting by a representative necessitated 1:1 calls to arrange the meeting, and sign anti-corruption due diligence forms before setting up the speaker contract. Lilly provided details of the speaker fees paid to the consultant in the last 6 months.

Lilly submitted that it did not know whether the consultant used its medicines to the exclusion of all others (although, from a practical standpoint, it doubted it). The representative's promotion of Lilly medicines to the consultant was within the Code and neither the representative nor the company would seek in any way to interfere with his prescribing decisions.

Lilly denied breaches of Clauses 18.1 and 19.1 of the Code.

PANEL RULING

The Panel noted its comments about Clause 15.4 at point 4 above and considered that they applied here. Whilst Lilly had not cited Clause 15.4 it had nonetheless responded in relation to the requirements of that clause.

The Panel noted its critical comments about Lilly's call record system at point 4 above and considered they were relevant here. In the last 6 months the consultant had presented at 11 Lilly sponsored meetings and had 17 1:1 meetings with the representative. The Panel noted Lilly's submission that its internal policies required 1:1 calls by the representatives to arrange the meeting and sign anticorruption and due diligence forms. The Panel queried whether a 1:1 meeting was indeed necessary to sign an anticorruption form on each occasion when the same speaker spoke at a series of company meetings in the same therapeutic area and was no doubt already familiar with the company's policies and procedures. Irrespective of the company's internal policy it was very difficult to see how 17 1:1 meetings in a six month period could meet the requirements of Clause 15.4 and its supplementary information.

Unlike its response at point 4 above Lilly did not quantify the number of calls solicited by the consultant. The Panel considered the arrangements unacceptable. The Panel considered that the totality of the evidence was such that on the balance of probabilities the number of meetings with the hospital consultant was inconsistent with Clause 15.4 and its supplementary information. A breach of Clause 15.4 was ruled. The Panel did not consider that there was evidence to establish that the meetings amounted to an inducement to prescribe Lilly's products or that the honoraria were otherwise unacceptable as alleged. No breach of Clauses 18.1 and 19.1 were ruled.

6 Referral to a hospital consultant

COMPLAINT

The complainant alleged that the representative pushed the local GPs to refer to the diabetes consultant at a local hospital who used Lilly products, and not to its local specialist team for insulins and diabetes management.

RESPONSE

Lilly understood that there were two local hospitals. A 'choose and book' system was used, whereby the GP and patient together could determine where the patient would like to obtain treatment.

Lilly also understood that the PBC had, until

recently, chosen the diabetes consultant as its lead consultant, but that at a meeting, in February 2009, members of the PBC group decided to work with a different diabetes consultant (of another hospital) (details of meetings 2 and 6, were provided).

Lilly had been unable to find anything to substantiate the allegation and the representative denied it.

Accordingly, this allegation was denied.

PANEL RULING

The Panel noted the complainant was anonymous and its comments in this regard at point 1 above. The Panel considered that there was no evidence that the representative had inappropriately pushed the complainant's GPs to refer patients to the hospital consultant as alleged. No breach of Clause 15.2 was ruled.

7 Alleged disparagement of diabetes service

COMPLAINT

The complainant alleged that the representative constantly criticised the local diabetes service, the members of its secondary care team and their competency in doing their jobs.

RESPONSE

The representative denied this accusation and Lilly would further note that several of the local clinicians – including the local diabetes consultant – participated in the diabetes course referred to at Point 1, which ran counter to this point.

Accordingly, this allegation was denied and Lilly denied breaching either Clause 2 of Clause 8.2 of the Code, or at all.

PANEL RULING

The Panel noted the complainant was anonymous and its comments in this regard at point 1 above. There was no evidence that the representative had behaved as alleged. No breach of Clauses 8.2 and 2 were ruled.

8 Hospitality

COMPLAINT

The complainant alleged that the representative had on many occasions taken GPs from the complainant's group out for a meal with no education – just a free meal.

RESPONSE

The representative denied this allegation. The representative had conducted 'group sells' in private rooms at local restaurants. Lilly enclosed details of the representative's group sells recorded on its call record system: all such group sells were conducted in accordance with the company's internal processes and procedures, had clear objectives and content. The provision of food or hospitality without associated educational content was not permitted under its internal rules and procedures or the Code. The representative knew this and his most recent training – on Lilly's Red Book, which underlined the company's core values of respect for people, integrity and excellence – was completed on 26 January 2009. The representative originally did his ABPI Code training in 1999, passing the exam in May 1999. The representative most recently had an update on the Code in September 2009.

Lilly stated that the three group sells which took place in restaurants (details of which were provided), were all approved, had clear objectives and content and fell within Lilly guidelines. In each case, the hospitality was secondary to the main purpose of the event. Lilly also enclosed copies of the Byetta (exenatide) group sell slides.

Accordingly, this allegation was denied.

In response to a request for further information Lilly explained that meetings in two named restaurants took place in private rooms at those restaurants. Each of the meetings was arranged by the PBC and sponsored by Lilly. As part of this sponsorship, the representative undertook a group sell presentation for the products mentioned in the screen shots supplied previously. The representative had confirmed that the invitations were sent by the PBC with a clear declaration of Lilly sponsorship. Consequently Lilly did not have copies of either the invitations or the agendas but offered to obtain them if required.

PANEL RULING

The Panel noted Lilly's submission that each of the meetings was arranged by the PBC and sponsored by Lilly. The company was unable to provide copies of the agendas or invitations. The representative gave a promotional talk at each meeting. Lilly should be able to demonstrate that the meetings were appropriate to sponsor and that the arrangements complied with the Code including the invitation and agenda. It was difficult to see how such meetings could be approved as submitted by Lilly without sight of the agenda or invitation. The Panel was very concerned about the apparent lack of control. There was, however, no evidence to support the allegation that the meetings comprised a free meal with no education. No breach of Clauses 2 and 19.1 were ruled.

9 Conduct of the representative

COMPLAINT

The representative also pushed constantly many of the complainant's GPs to switch their patients from a competitor insulin to a Lilly insulin.

RESPONSE

As a pharmaceutical diabetes representative, a key part of the representative's role was the promotion of patient safety and well-being, in addition to the promotion of Lilly medicines. As part of his work, where the health professional asked for suggestions as to how the care of an individual patient might be improved, the representative might legitimately properly promote a Lilly product, within the scope of the Code: he and Lilly would, however, not advocate switching patients from one therapy to another if they were well-controlled on their current regime. Lilly enclosed copies of promotional materials used by its representatives.

The allegation was denied.

Lilly stated that it strove to ensure that its dealings with health professionals were ethical, complied with the Code and of the highest professional standards. The company had concluded, from its investigation into the matters above, that the representative at issue had not acted unethically or breached Clauses 15.2 or 15.3 of the Code; Lilly had not brought discredit to the pharmaceutical industry at (Clause 2).

PANEL RULING

The Panel considered its ruling at point 3 above was relevant here. The Panel ruled no breach of Clause 15.2 of the Code.

Complaint received **25 March 2009**

Case completed **24 June 2009**