ANONYMOUS PHARMACIST v LILLY

Nurse Education Service

An anonymous, non-contactable practice pharmacist alleged that a medical education programme offered by Eli Lilly and Company was a thinly disguised method of promoting products and its implementation had been unprofessional.

The complainant noted that the programme was sold as a mentorship scheme to help local practice nurses manage diabetes. An independent company provided the nurses. The complainant considered that the company's name, which was a play on NHS lettering, was odd and looked like passing off.

The complainant described how a representative had arranged a meeting at his/her practice with the lead diabetes GP and nurse to explain the service; in reality the meeting was arranged merely to fill out a form to take some IT information and to book an appointment for the nurse to visit. It was clear that the representative had 'attached' him/herself to the educational programme. It was made clear that the representative was there in a non-promotional capacity and did not discuss product. A couple of days later, however, the representative returned to make appointments to discuss products despite knowing the practice's robust policy for seeing representatives. The practice manager naively felt obliged to agree to a meeting due to the service being offered. The complainant was concerned that the representative had obtained a number of contacts within the practice on the back of delivering an educational service including a sales presentation in a very short time period. Such behaviour did the industry no credit.

The complainant noticed a significant increase in the use of Lilly's diabetes medicine and referred, *inter alia*, to a series of tutorials run by the service nurse which each ended with a very positive message for the Lilly product relative to the alternatives. In addition, the practice nurse felt that she had been overwhelmed by requests to see the Lilly representative. The complainant considered that his/her practice had been 'targeted' during the service and described similar events and an increase in the use of Lilly products at other local practices as a disgraceful trend.

The detailed response from Lilly is given below.

The Panel noted that the complainant was anonymous and non-contactable. 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 allegations concerned not only what happened at the complainant's surgery but also a broader allegation about local implementation of the service. The complainant had not identified his/her surgery, although he/she had identified the region. It was not possible to contact the complainant for further information.

The Panel noted that the Enhanced Management of Diabetes (EMD) service was described as a clinical mentorship programme to support confidence and capability in managing type 2 diabetes. According to the EMD service detail aid, the service aimed to support the diabetes quality outcomes framework as part of the quality, innovation, productivity and prevention (QIPP) agenda; for the diabetes specialist to support appropriate referrals and patient care; and for the primary care health professional to build confidence and capability in managing type 2 diabetes.

The Panel noted that representatives briefly introduced the service to practices at a promotional call. Subsequently at a non-promotional call the representative would present the service and complete the Practice Authorisation Form which had to be signed by two GPs. The representative then set up the initial meeting with the service nurse who thereafter ran the service. The EMD service was anticipated to require approximately 5 service days to deliver in an average 3 GP practice.

The service comprised four steps. Firstly, patients were selected who would benefit from review to improve health outcomes. Subsequently, there was a patient review meeting which comprised training and a case note review of suboptimally controlled patients in line with national guidelines. The nurse delivered a tailored clinical mentorship programme on the management of type 2 diabetes which comprised training modules chosen by the practice according to need. The final section of each module discussed relevant medicines. It did not appear that any module gave disproportionate emphasis to Lilly products or ended with a very positive message for such products as alleged.

At patient review meetings the practice diabetes team identified suboptimally controlled patients who should be invited for clinical review. The EMD service Nurse Brief referred to the GP's clinical assessment of each patient and him/her deciding which form of treatment or non-medical intervention would be most appropriate for that patient. The GP had to sign the Practice Treatment Protocol. The service nurse could not write prescriptions, recommend a specific medicine or implement a switch service. The EMD Nurse Brief explained that following the case notes review individual patients should be allocated to one of the following: education and counselling; oral therapy; glucagon-like peptide-1 (GLP-1) agonists and insulin therapy. Each intervention would only be decided following a face-to-face consultation and clinical assessment to establish whether the patient had received

maximum benefit from his/her current regimen. Educational and lifestyle counselling would be provided in isolation of any other intervention.

Identified patients were then invited to a clinic attended by the service nurse, practice nurse or GP. The EMD service Nurse Brief explained that the role of the service nurse was to support and mentor the nominated member of staff. A detailed clinic assessment sheet for each patient consultation was presented by the practice nurse/GP to the lead GP to authorise action in alignment with treatment protocol.

The Panel noted the complainant's allegation that the name of the third party service provider played with NHS lettering and thus looked like passing off. The Panel accepted that the name of the third party provider was not wholly dissimilar to NHS but did not consider that the complainant had provided any evidence to establish that health professionals had been confused or otherwise misled by the name of the organisation. No breach was ruled.

The Representative EMD Service Briefing Document made clear that representatives could only provide administrative support in relation to service delivery and that support of a project must not be dependent on the customer prescribing specific medicines. Prescribing of specific products must not be linked to the service either in conversation or in writing with any customer. One page discussed the practice authorisation form and stated 'Networking key personnel within the practice, by the Lilly/[named pharmaceutical company] representative, to ensure an understanding and commitment to the EMD service has been achieved will enable the service to be implemented in a timely and efficient manner'. In response to the statement 'I don't want lots of representatives coming to see how I'm getting on with the programme!' the representatives' Q&A document explained that the representative's role was 'purely administrative and to guide you through the Authorisation Documentation. All other discussions in relation to service provision should be held between you and the Service Nurse Advisor'.

The EMD representatives' training slides included a section themed 'Working Ethically with Nurse Support Programmes', within which a slide stipulated, *inter alia*, 'Keep any promotional activity separate from EMD discussions. A separate customer meeting should be made to discuss EMD', 'Do not work in any EMD practices within 24 hours of the EMD nurse advisor working there' and 'Ensure EMD plans are separated from any business plans'. A subsequent slide headed 'Maintain your account' advised 'Call in and ask if they are happy with the service, do they need any further support (not 24 hours either-side of a service day)'. Such guidance regarding the '24 hour rule', contrary to Lilly's assertion was not clearly stated in the representatives' briefing guide. In the Panel's view companies should be mindful of the impression given by the presence of the representative at the practice during the provision of the service. The Panel considered it would be helpful if there was detailed written guidance on the acceptability or otherwise of promotional calls during the period of time that the EMD service was provided and was particularly concerned that in the absence of such guidance representatives were encouraged to visit practices during the provision of the service as long as the visit was more than 24 hours either side of the nurse advisor working there. The Panel queried whether this, in conjunction with the direction to network at the practice, might result in a practice not fully understanding the difference between the representatives' promotional and non-promotional roles.

The Panel noted Lilly's submission about the number of calls by representatives in relation to Lilly's medicines at the practices that underwent the EMD service between 2012 and 2014. The Panel was extremely concerned that no representative EMD service calls were recorded from 2012 – 2014 despite the implementation of 9 services. Lilly estimated a minimum of 3 such calls per practice. The Panel therefore queried how reliable the recorded call rates were generally. In addition it appeared that Lilly did not record telephone requests for visits which in the Panel's view was unusual.

Whilst the Panel had concerns about the management of representatives, in particular the failure to record any local service calls as set out above, it also noted its comments above about the burden of proof. The complainant's surgery had not been identified and thus it was not possible to determine precisely what had occurred there. Similarly it was not possible to determine precisely what had occurred within the region. In such circumstances the Panel ruled no breach of the Code in relation to the conduct of the representative.

The Panel noted the complainant's allegation that the service nurse provided biased education and the service led to a disproportionate prescribing of Lilly/[named pharmaceutical company] products. The Panel noted the details of the EMD service and its comment above that it did not appear that any module gave disproportionate emphasis to Lilly products as alleged. The Panel noted that the Code stated that service providers must operate to detailed written instructions provided by the company similar to the briefing material for representatives. The Panel was concerned about the failure to provide any formal briefing to the service nurses on how the training modules were to be used within GP practices. This was especially so given the modules discussed products. The Panel noted Lilly's submission that the service nurses were 'independent diabetes specialists who trained themselves on the module'. The Panel had no way of knowing what was said by the service nurses during the training sessions.

The Panel noted its general comments and concerns about the service but bore in mind that the complainant had to establish his/her case on the balance of probabilities. On balance the Panel did not consider that there was sufficient evidence to establish whether, either at the complainant's surgery or elsewhere locally, the service had been offered in connection with the promotion of medicines or otherwise as an inducement contrary to the Code; no breach was ruled. Similarly the Panel

did not consider that there was evidence to show that the EMD service was a disguised promotional activity; no breach of the Code was ruled.

The Panel noted its general comments above about the service. Whilst some concerns were outlined above the Panel did not consider that there was any evidence before it to demonstrate that the service as implemented in the complainant's surgery or elsewhere in the region was biased towards Lilly products as alleged. Consequently the Panel ruled no breach of the Code.

Noting its rulings above, the Panel ruled no breaches of the Code including no breach of Clause 2.

An anonymous, non-contactable complainant who described him/herself as a practice pharmacist complained about a medical education programme offered by Eli Lilly and Company Ltd.

COMPLAINT

The complainant explained that from local discussions about the programme he/she was concerned that it was a thinly disguised method of promoting products and represented a very serious breach of the Code.

The complainant stated that an arrangement with two local primary care trusts (PCTs), which were now clinical commissioning groups (CCGs), was made with the local Lilly sales manager for the Lilly nurse education service to be offered to practices. It was sold as a mentorship scheme to support local practice nurses in managing diabetes. An independent company provided the nurses. The complainant considered that the name of the company was a play on NHS lettering which was odd and looked like passing off. The complainant stated that on paper it looked like a useful education service, however the implementation had been very unprofessional and showed that the pharmaceutical industry had not changed at all. That was the complainant's experience and from discussions with local colleagues, it was repeated locally.

The complainant explained that a representative had called into the practice, asked to see the practice manager and stated that he/she worked on behalf of the then PCT to deliver diabetes training. The representative asked the manager to arrange a meeting with the lead diabetes GP and nurse to explain the service. The complainant was invited to attend the meeting and stated that in reality the meeting was arranged merely to fill out a form with the doctors' names and numbers, to take some IT information and to book an appointment for the nurse to visit. Such information could have been obtained from the practice manager but it was clear that the representative had 'attached' him/herself to the educational programme. It was made clear that the representative was there in a non-promotional capacity and did not discuss product.

However, a couple of days later the representative returned and asked to see the practice manager who assumed it was in relation to the programme; it was actually to request appointments and meetings with the practice to discuss products. The complainant stated that as the practice had a robust policy for seeing representatives which the representative was aware of, it was clear that the programme was being misused to secure a promotional opportunity. The complainant was convinced that this must be outside the 'spirit' of the Code. The practice manager naively felt obliged due to the service being offered and agreed to set up a meeting which caused disruption at the practice now that the manager understood how the representative had behaved.

The complainant was concerned that the representative had managed to obtain a number of contacts within the practice on the back of delivering an educational service leading up to and including a sales presentation to those people in a very short time period. The complainant alleged that it was disgraceful behaviour and did the pharmaceutical industry as a whole no credit.

The complainant stated that worse followed. In a routine review of the practice's prescribing data, he/she noticed a significant increase in the use of Lilly's medicine for diabetes. Previously the practice had a reasonable distribution of products as its formulary recognised the need to offer a wide range of alternatives, particularly insulin.

The complainant stated that on speaking with the practice nurse, it became clear that the service nurse had guided the practice nurses towards Lilly's medicines. The service nurse ran a series of tutorials with slides on aspects of diabetes. In every case, the scenario ended with a very positive message for the Lilly product relative to the alternatives. The complainant alleged that this biased education had led to medicine selection that favoured Lilly and he/she understood from a representative of a competitor company that there had been extensive inter-company discussions about this issue.

In addition to the service nurse activity, the practice nurse felt that she had been overwhelmed by requests to see the Lilly representative as well as those from the other named pharmaceutical company which co-sponsored the programme. The complainant considered that his/her practice had been 'targeted' by the sponsoring companies during the service nurse activity.

The complainant was sure that the Authority would review the number of visits made by representatives to practices which had used the service nurse service and was equally sure that it would exceed what the Code considered acceptable.

The complainant stated that having spoken with colleagues in other practices, multiple visits by representatives to set up an education service, rapid follow-up opportunities to sell products, almost carpet bombing practices whilst the nurse was working, biased education, advice from the service nurse and a disproportionate increase in the prescribing of Lilly diabetes products seemed to be a trend which was absolutely disgraceful.

When writing to Lilly, the Authority asked it to respond in relation to Clauses 2, 7.2, 9.1, 12.1, 15.2, 15.3, 15.4, 18.1 and 18.4 of the Code.

RESPONSE

Lilly explained that the nurse education service referred to was the Enhanced Management of Type 2 Diabetes (EMD) training programme initiated in 2012 in the locality of the complainant's practice until March 2014. The service was undertaken on behalf of Lilly by an independent company. In 2012 it was co-sponsored by Lilly and another pharmaceutical company. Subsequently and until its completion it was sponsored by Lilly.

Lilly submitted that the complaint lacked important information that would have allowed it to identify the alleged behaviour complained about; there were no specific dates or practice locations identified, although it was clearly sited in a named region. Lilly stated that any further information about the alleged behaviour would be helpful.

Lilly submitted that the EMD service was a UK wide service run in GP practices throughout the UK. Lilly was very disappointed to receive a complaint about the service as it took its obligations under the Code very seriously. Lilly conducted an investigation and refuted all allegations of improper conduct or Code breaches as alleged by the complainant.

Lilly submitted that it had a business relationship with the named CCGs. Lilly's healthcare development manager (HDM) spoke with various members of the local CCGs in the course of her business. These calls could be about Lilly service offerings such as the EMD service, or about its medicines. None of the calls were about service offerings and Lilly medicines. During 2012-2014, the HDM recorded 64 calls to 30 individuals at the named CCGs, 35 of which were about service offerings including the EMD service, 29 were about Lilly medicines.

The EMD service was a clinical mentorship programme designed to support confidence and capability development in the management of type 2 diabetes in primary care. Nine local practices received the EMD service during 2012-2014.

As set out in the EMD service leavepiece, the EMD service detail aid, the EMD service included four parts as follows:

1 Patient selection for clinical review using data collection software.

2 Case notes review from patients identified at stage 1. A tailored education and training programme using the EMD service modules. These modules were optional and practices selected the modules that they identified as being relevant to them. The optional tailored education consisted of 4 modules:

- Module 1 Oral Optimisation, focussed on applying National Institute for Health and Care Excellence (NICE) guidelines and optimising all therapies,
- Module 2 Beyond Oral Therapies, focussed on principles of management following failure of oral therapies,
- Module 3 Early Insulin Usage, focussed on maximising the first step in insulin therapy,
- Module 4 Insulin Optimisation, focussed on maximising glycaemic control in patients suboptimally controlled on insulin.

3 Joint diabetes clinic when a nominated practice nurse conducted a diabetes review clinic supported and mentored by the service nurse.

4 Pre/post practice report with key indicators, the EMD service practice report was completed by the service nurse advisor stating what had been done.

The representative referred a practice for an EMD service to the service organisation and then provided only administrative support. This support involved guiding the health professional through the authorisation documentation and setting up the meeting with the service nurse. This was clearly stated and outlined in the representatives' briefing document and the EMD Nurse Brief. Following a practice referral by a representative and setting up the initial meeting, all other discussions in relation to the service provision were held between the health professional and the service nurse.

In the representatives' briefing document, it was clearly stated that the representative could only provide administrative support in relation to service delivery. It was also stated that the support of this project must not be dependent on the customer prescribing a Lilly product. The prescribing of specific products must not be linked to the service either in conversation or in writing with any customer. In addition, it clearly stated that a detailed discussion about the EMD service could only take place during a non-promotional call and must not be instigated at the same time as a call at which products were promoted.

The Lilly representative completed the practice details on an EMD service Practice Authorisation Form, obtained signature(s) and then scheduled a meeting between the practice and a service nurse usually whilst in the identified surgery in the presence of the practice manager.

The service nurse's responsibilities were set out in the EMD Nurse Brief. The nurse advisor could not and was not allowed to write prescriptions, recommend a specific medicine, or implement a switch service. Service nurse advisors were bound by their ethical obligations.

The HDM in question worked for Lilly during 2012-2014. Her role included liaising with commissioning groups, including those in the named region. The HDM had no direct involvement with the setup or delivery of the service.

The EMD service was one service run nationally and thus there was no local representatives' training material. Representatives were provided with the representatives' briefing document, a Q&A

document and the EMD service material, ie the EMD service leavepiece and the EMD service detail aid.

Nationally representatives could introduce the EMD service to relevant healthcare providers as outlined in the representatives' briefing document, the EMD service leavepiece and the service detail aid. If a practice was interested in the EMD service then it could be signed up as described above. The way practices chose to take various parts of the EMD service was described above.

Lilly recognised that to successfully manage diabetes, health professionals and patients needed support to address the daily challenges of diabetes. Lilly appointed the service organisation to supply the EMD service in 7 February 2012. It was a respected company providing nurse services to third parties such as Lilly. Copies of relevant material provided by the service organisation and Lilly about the EMD service were provided.

The implementation of the EMD service was described in the nurse brief in a full page service process flow diagram showing responsibilities and activities.

The service organisation maintained records of practice staff who participated in the EMD service. This information was not shared with Lilly. The EMD service was provided by the service organisation entirely without involvement or influence by Lilly. The GP practices identified their own staff to participate in the EMD service.

Lilly representatives had all passed the ABPI Medical Representatives' Examination and were only instructed to make calls as outlined in Clause 15. If a call was about the EMD service then the procedure as described in the representatives' briefing document must be followed.

During 2012-2014, all the calls recorded, concerned Lilly medicines not service offerings such as the EMD service made by Lilly representatives in 6 of the 9 practices where EMD service was completed locally. In the remaining 3 practices where the EMD service was completed there were no recorded calls concerning Lilly medicines.

Summary

All of the materials relating to the provision of the EMD service were reviewed and certified by company signatories.

The service was clearly identified as being provided and sponsored by Lilly and the other named company. The companies' logos were on materials and the sponsorship position was made clear in all discussions.

In summary, Lilly stated that the EMD service enhanced patient care and benefited the NHS. The provision of the service was strictly non-promotional and not connected with the sale of any individual Lilly products or those of its former co sponsor. Lilly submitted that its representatives and the service provider had not made or implied a link between this service and the companies' products. The EMD service was not a disguised method of promoting products.

For all these reasons, Lilly did not consider that it had brought discredit upon or reduced confidence in the pharmaceutical industry and denied that it had breached Clause 2 or Clauses 7.2, 9.1, 12.1, 15.2, 15.3, 15.4, 18.1 and 18.4.

In response to a request for further information from the Panel, Lilly submitted that the service organisation trained service nurses for the EMD service; there was no specific briefing document on the four training modules. The service nurses were independent diabetes specialists who trained themselves on the modules. Lilly submitted that a newly recruited service nurse could have been trained on the modules by one or more of the more experienced service nurses. Lilly noted that the service organisation refuted the allegation that its service nurse had guided the practice nurse towards Lilly medicines and had provided biased education that favoured the selection of Lilly medicines. The service organisation clearly stated that its service nurse could not and would not write prescriptions, recommend specific products or implement a switch service.

Lilly submitted that the service nurse's role was to mentor and educate the practice on the management of diabetes in line with NICE guidance resulting in improved patient outcomes through optimised care and the four modules were tools used in that task. The modules covered the licensed products within each therapeutic group and had no bias towards any medicine.

Lilly conducted further investigations and confirmed that there was no guidance document on promotional calls to EMD practices whether from national or local senior sales teams or otherwise. Lilly had provided the EMD training slides used for national representatives which instructed representatives not to discuss products during the EMD service call and not to work with a participating EMD practice within 24 hours of the service nurse working there. These instructions were reinforced and clearly stated in the representatives' briefing guide and repeated to representatives on a regional basis by the district sales managers including the named area. Lilly refuted that its representative had used the EMD service to secure a promotional opportunity as alleged.

Lilly gave details of the calls made by the HDM between 2012 and 2014; 29 calls related to Lilly medicines and 35 calls related to services such as the EMD service in local practices. All of these calls were made at the administrative offices of the local PCT.

Lilly submitted that the representative's 29 calls made to the 9 EMD practices during 2012-2014 were all related to Lilly medicines; no EMD service calls were recorded. Lilly assumed, however, that at least 3 calls per practice would have been made, one to

introduce the service, one for information and one follow up call, indicating that another estimated 27 calls were made by the representative for the EMD service. Lilly had no record of telephone requests for such meetings or calls. A summary of the representative's calls was provided.

Lilly explained that there were no recorded calls in relation to service offerings such as the EMD service. In response to a request for further information in relation to each of the 29 calls made by the Lilly representative to the 9 practices within Blackpool & Fylde between 2012 and 2014 Lilly provided the following details:

- practice 1, the EMD service ran January – June 2012, no product calls made
- practice 2, the EMD service ran May – October 2012, two product calls made
- practice 3, the EMD service ran May – February 2013, four product calls made
- practice 4, the EMD service ran January – July 2012, three product calls made
- practice 5, the EMD service ran January – July 2012, no product calls made
- practice 6, the EMD service ran October 2013 – March 2014, no product calls made
- practice 7, the EMD service ran January 2011 – January 2012, no product calls made
- practice 8, the EMD service ran January – July 2012, no product calls made
- practice 9, the EMD service ran May – November 2013, no product calls made.

In conclusion, Lilly stated that its EMD service had enhanced patient care and benefited the NHS. Service provision had been strictly non-promotional and not connected with the sales of any Lilly products. The representatives and the service provider had not made or implied a link between the service and Lilly products.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. 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 allegations concerned not only what happened at the complainant's surgery but also a broader allegation about local implementation of the service. The complainant had not identified his/her surgery, although he/she had identified the region. It was not possible to contact the complainant for further information.

The Panel noted that a named pharmaceutical company had co-sponsored the EMD service with Lilly between January and December 2012. The complainant had referred to that company solely in relation to the number of requests made by representatives from both companies to see the practice nurse at the complainant's surgery during the EMD service. All of the documents provided by Lilly including those given to health professionals and patients still incorporated the other company's name and/or corporate logo. The Panel noted that the case preparation manager had not taken the matter up with that other company at the outset nor on receipt of Lilly's response. The Panel noted that under the Constitution and Procedure it had no power to either refer the matter directly to the pharmaceutical company or request the case preparation manager to do so.

Clause 18.4 provided that medical and educational goods and services must enhance patient care or benefit the NHS and maintain patient care. The relevant supplementary information provided further guidance about the implementation of such services and the limited role of representatives. Representatives could introduce a service by means of a brief description and/or delivering materials but could not instigate a detailed discussion about the service at the same time as a call at which products were promoted. Reference was made to representatives providing administrative support in relation to the provision of a service. The relevant supplementary information made it clear that Clauses 18.1 and 18.4 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another. A therapeutic review which ensured that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support.

The Panel noted that the EMD service was described as a clinical mentorship programme to support confidence and capability in managing type 2 diabetes. According to the EMD service detail aid, the service aimed to support the diabetes quality outcomes framework as part of the quality, innovation, productivity and prevention (QIPP) agenda; for the diabetes specialist to support appropriate referrals and patient care; and for the primary care health professional to build confidence and capability in managing type 2 diabetes.

The Panel noted that representatives could briefly introduce the service to practices at a promotional call using the EMD leavepiece. Subsequently at a non-promotional call the representative would present the service using the EMD service detail aid and complete the Practice Authorisation Form which outlined service implementation, contact details and had to be signed by two GPs. The representative then set up the initial meeting with the service nurse who thereafter ran the service. The EMD service was anticipated to require approximately 5 service days to deliver in an average 3 GP practice.

The service comprised four steps. Firstly, patients were selected for clinical review via a data collection search which included a baseline review of all diabetics highlighting those who would benefit from review to improve health outcomes. An initial outcome report was provided to the practice. Subsequently, there was a patient review meeting which comprised training and a case note review of suboptimally controlled patients in line with NICE

guidelines 2009. The nurse delivered a tailored clinical mentorship programme on the management of type 2 diabetes which comprised training modules chosen by the practice according to need. The four available training modules were 'Oral optimisation, Applying NICE guidelines and optimising oral therapies; Beyond Oral Therapies, Principles of management following failure of oral therapies; Early Insulin Usage, Maximising the first step in insulin therapy; and Insulin Optimisation, Maximising glycaemic control in patients suboptimally controlled on insulin'. The first four sections of each module were identical and covered diabetes in the UK, diagnosis criteria, aims of management and managing poor control. The final section of each discussed relevant medicines. It did not appear that any module gave disproportionate emphasis to Lilly products or ended with a very positive message for such products as alleged. Medicines were discussed in relation to relevant NICE guidelines and details of common side effects and contraindications were given. Readers were referred to the products' summaries of product characteristics (SPCs) for further information.

The patient review meeting was attended by the service lead GP and his/her diabetes team to identify suboptimally controlled patients and should be invited in for clinical review. The EMD service Nurse Brief referred to the GP's clinical assessment of each individual patient and him/her deciding which form of treatment or non-medical intervention would be most appropriate for that patient. The GP had to sign the Practice Treatment Protocol which covered patient identification; patient review including an education and training workshop and the role of the service nurse advisor; the nurse clinic process, clinic content and logistics, the NICE treatment algorithm 2009 and an alternative practice treatment algorithm. The selected treatment algorithm had to be signed by the GP. It was made clear that the nurse advisor could not write prescriptions, recommend a specific medicine or implement a switch service. The EMD Nurse Brief explained that the case notes review should result in individual patients being allocated to one of the following treatment arms: education and counselling; oral therapy; glucagon-like peptide-1 (GLP-1) agonists and insulin therapy. Each intervention would only be decided following a face-to-face consultation including a clinical assessment to establish whether the patient had received maximum benefit from his/her current regimen. Educational and lifestyle counselling would be provided in isolation of any other intervention.

Identified patients were invited to a clinic attended by the nurse advisor, practice nurse or GP. The EMD service Nurse Brief explained that the nurse's role was to support and mentor the nominated member of staff as he/she commenced a comprehensive clinic assessment of patients enabling him/her to transition the training received into practical experience of managing patients suboptimally controlled on their current therapies. A detailed clinic assessment sheet for each patient consultation was presented by the practice nurse/GP to the lead GP to authorise action in alignment with treatment protocol. All patients received patient education and counselling from the practice nurse.

The Panel noted the complainant's allegation that the name of the third party provider played with NHS lettering and thus looked like passing off. The Panel noted that the complainant had incorrectly referenced the name of the organisation. The Panel noted that according to the representatives' Q&A document in response to someone stating 'I have never heard of [service company]' representatives were told to refer to the rigorous selection process and explain that it was a healthcare agency which was also an independent service provider to the NHS. The Panel accepted that the name of the service organisation was not wholly dissimilar to NHS but did not consider that the complainant had provided any evidence to establish that health professionals had been confused or otherwise misled by the name of the organisation. No breach of Clause 7.2 was ruled.

The Panel noted the allegation about the conduct of a representative at the complainant's surgery and a general allegation that such conduct was repeated locally. The Panel noted its comments above about medical and educational goods and services and the limited role of representatives as set out in the supplementary information to Clause 18.4 and Lilly's description of the representatives' role.

The Representative EMD Service Briefing Document outlined the service, the roles and responsibilities of the service nurse and the relevant requirements of the Code. It was made clear that representatives could only provide administrative support in relation to service delivery and that support of a project must not be dependent on the customer prescribing a Lilly product. Prescribing of specific products must not be linked to the service either in conversation or in writing with any customer. Page 15 discussed the practice authorisation form and stated 'Networking key personnel within the practice, by the Lilly/ [named former co-sponsor] representative, to ensure an understanding and commitment to the EMD service has been achieved will enable the service to be implemented in a timely and efficient manner'. In response to the statement 'I don't want lots of representatives coming to see how I'm getting on with the programme!' the representatives' Q&A document explained that the representative's role was 'purely administrative and to guide you through the Authorisation Documentation. All other discussions in relation to service provision should be held between you and the Nurse Advisor'.

The EMD representatives' training slides included a section themed 'Working Ethically with Nurse Support Programmes', within which a slide headed 'In a Nutshell' stipulated, *inter alia*, 'Keep any promotional activity separate from EMD discussions. A separate customer meeting should be made to discuss EMD', 'Do not work in any EMD practices within 24 hours of the EMD nurse advisor working there' and 'Ensure EMD plans are separated from any business plans'. A subsequent slide within the section themed 'EMD – A Representative's Perspective' was headed 'Maintain your account' and advised 'Call in and ask if they are happy with the service, do they need any further support (not 24 hours either-side of a service day)'. Such guidance regarding the '24 hour rule', contrary

to Lilly's assertion was not clearly stated in the representatives' briefing guide. In the Panel's view companies should be mindful of the impression given by the presence of a representative at a practice during the provision of a service given the requirements of Clause 18.4 and its supplementary information. The Panel considered it would be helpful if there was detailed written guidance on the acceptability or otherwise of promotional calls during the period of time that the EMD service was provided and was particularly concerned that in the absence of such guidance representatives were encouraged to visit practices during the provision of the service as long as the visit was more than 24 hours either side of the service nurse working there. The Panel queried whether this, in conjunction with the direction to network at the practice, might result in a practice not fully understanding the difference between the representatives' promotional and non-promotional roles.

The Panel noted Lilly's submission about the 29 calls by representatives in relation to Lilly medicines at the 9 practices that underwent the EMD service between 2012 and 2014. The Panel was extremely concerned that no representative EMD service calls were recorded from 2012 – 2014 despite the implementation of 9 services. Lilly estimated a minimum of 3 such calls per practice. The Panel therefore queried how reliable the recorded call rates were generally. In addition it appeared that Lilly did not record telephone requests for visits which in the Panel's view was unusual. The Panel had no information about the activity of representatives from the co-sponsor of the service.

Whilst the Panel had concerns about the management of representatives, including the failure to record any service calls in the named region, it also noted its comments above about the burden of proof. The complainant's surgery had not been identified and thus it was not possible to determine precisely what had occurred there. Similarly it was not possible to determine precisely what had occurred within the local region. The Panel did not consider that the number of regional calls made during service implementation was such that representatives were 'carpet bombing' practices as alleged. In such circumstances the Panel ruled no breach of Clauses 15.2, 15.3, and 15.4 of the Code.

In relation to the EMD service, the Panel noted the complainant alleged that both at his/her practice and elsewhere the service nurse provided biased education and the service led to a disproportionate prescribing of the companies' products. The Panel noted the details of the EMD service including the training modules set out above. The Panel noted its comment above that it did not appear that any module gave disproportionate emphasis to Lilly products as alleged. The Panel noted that the supplementary information to Clause 18.4 Provision of Medical and Educational Goods and Services, stated that service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The Panel was concerned about the failure to provide any formal briefing on how the four training modules were to be used within GP practices. This was especially so given the modules discussed products. The Panel noted Lilly's submission that the service 'nurses were 'independent diabetes specialists who trained themselves on the module'. The Panel had no way of knowing what was said by the nurses during the training sessions.

The Panel noted its general comments and concerns about the service set out above but bore in mind that the complainant had to establish his/her case on the balance of probabilities. On balance the Panel did not consider that there was sufficient evidence to establish whether, either at the complainant's surgery or locally, the service had been offered in connection with the promotion of medicines or otherwise as an inducement contrary to Clause 18.1. No breach of that clause was ruled. Similarly the Panel did not consider that there was evidence to show that the EMD service was a disguised promotional activity; no breach of Clause 12.1 was ruled.

The Panel noted its general comments above about the service. Whilst some concerns were outlined above the Panel did not consider that there was any evidence before it to demonstrate that the service as implemented in the complainant's surgery or locally was biased towards Lilly products as alleged. Consequently the Panel ruled no breach of Clause 18.4.

Noting its rulings above the Panel ruled no breaches of Clauses 9.1 and 2.

Complaint received **23 May 2014**

Case completed **1 September 2014**