ANONYMOUS, NON CONTACTABLE v SANOFI

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

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

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

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

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

The detailed response from Sanofi is given below.

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

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

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

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

The Panel noted Sanofi had only worked with the training and consultancy company to provide a patient management and nurse advisor service for patients. The Panel noted that according to the Service Operating Procedure the service was a medical and educational goods and service (MEGS) which included a review of patients' current treatment regimen in line with locally agreed guidance and ran from early 2014 until February 2015.

The Panel noted that although the named health professional originally requested the service and that it be delivered by his/her training and consultancy company, the service was described in the consultancy services agreements as a service to medicine developed by Sanofi. Sanofi was thus

responsible under the Code for it. The agreements stated that the role of the training and consultancy company was to deliver the service and undertake patient assessment clinics.

The Panel noted that according to the service operating procedure the service was to be offered, unrestricted, to local practices upon health care provider request by an NHS outcome manager (NOM) if the practice satisfied certain criteria. If the NOM was satisfied that these criteria were met a Sanofi medical manager would then contact the named health professional who would deliver the service as set out in the service operating procedure via his/her training and consultancy company.

The Panel noted that the objective of the service was to help patients effectively improve control of their condition and reduce their risk of complications. According to the service operating procedure, specialist nurses employed by the training and consultancy company, or the named health professional in question, individually assessed patients and reviewed their treatment in line with locally agreed guidance provided by the practice so that there was clarity on treatment. The locally agreed guidance would include national guidance/treatment pathways. An agreement between the training and consultancy company and each individual practice provided that 'the practice would at all times retain clinical responsibility for the management of patients under its care including but without limitation all prescribing decisions and patient management'.

The Panel noted Sanofi's submission that local sales data showed that the service did not directly affect the uptake of Sanofi products in those practices that received the service. Taking all the circumstances into account the Panel considered that the complainant had not established that the provision and operation of the management and nurse advisor service was an inducement to prescribe or otherwise contrary to the Code as alleged. High standards had been maintained. No breaches of the Code were ruled including no breach of Clause 2.

There was no evidence that Sanofi had employed the named health professional as a consultant. No breach of the Code was ruled.

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

COMPLAINT

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

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

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

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

The complainant stated that the amount of money that industry had pumped into these courses was staggering, and in his/her opinion the risk that the support could be perceived as an attempt to 'buy the business' had led him/her to continuously try

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

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

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

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

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

RESPONSE

Sanofi confirmed that it had previously worked with the training and consultancy company to provide a patient management and nurse advisor service for relevant patients, but had not worked or funded initiatives with that company to perform either clinical audits in healthcare organisations or to undertake training workshops in the specified therapeutic area.

Sanofi submitted that its relationship with the training and consultancy company was to provide a patient management and nurse advisor service between November 2013 to February 2015 which was delivered as a medical and educational goods and service (MEGS) agreement. Sanofi summarised the history of the MEGS programme using the services of the training and consultancy company which ran in a number of primary care practices in a particular region. Relevant supporting documentation was referred to and provided.

The named health professional first approached Sanofi in late 2013 for his/her training and consultancy company to provide a nurse-led service in selected local GP practices. It was decided in 2013 to contract with the training and consultancy company to run the proposed review in two GP practices and to undertake twelve patient assessment clinics in these practices. The nurse-led service was to be offered as a MEGS programme with the initial contract between Sanofi and the training and consultancy company covering a 2 month period from the end of 2013.

A service operating procedure was created for this service and was certified and approved as a non-promotional item. The Sanofi medical affairs and NHS liaison teams at the time dealt directly with the named health professional and the training and consultancy company in setting up the MEGS agreement and service offering.

The service operating procedure outlined the scope and objectives of the nurse-led service. The objective

of the service was to help patients with a specific condition improve their control and reduce their risk of developing related complications. The training and consultancy company employed specialist nurses to work in primary care alongside the existing practice nurse teams in each organisation. These specialist nurses offered to individually assess patients and to review their current treatment regime in line with locally agreed guidance. The service was to be offered to those healthcare organisations which aimed to improve the healthcare of this group of patients. The service operating procedure outlined that all decisions regarding medicine management following an individual patient assessment review would be based on individual clinical need and in line with local and national guidance. Following a patient review by the training and consultancy company nurse-led team, all decisions regarding medicines would be made by the appropriate health practitioner or the practice's own specialist nurse advisor in strict compliance with a prescribing protocol agreed by the respective healthcare organisation. In addition, Section 5.1 of the signed contract between Sanofi and the training and consultancy company clearly outlined that the MEGS agreement was not an incentive or reward for a person's past, present or future willingness to prescribe, administer, recommend, purchase, consume, use, pay for, reimburse, authorise, approve or supply any product sold or provided by Sanofi.

The initial consultancy agreement and contract between Sanofi and the training and consultancy company was extended and updated in early 2014 and specified that the training and consultancy company would conduct further individual patient assessment clinics in January and February 2014 as detailed. The scope and objectives of the nurse-led service remained identical to that originally agreed.

A new agreement and contract was made with the training and consultancy company to continue the service from 3 March 2014 until the end of 2014. The MEGS service delivery programme was identical to that detailed above and operated according to the previously approved service operating procedure. During 2014, the training and consultancy company carried out between 5 and 15 individual patient assessment clinics per week involving up to fourteen GP practices and community-based hospitals in four CCGs.

Sanofi terminated its agreement with the training and consultancy company on 28 February 2015 following a decision to work with another healthcare company as the provider of a MEGS based programme to provide a nurse advisory service for practices managing such patients nationally. Sanofi had therefore not worked directly with the training and consultancy company and the named health professional since March 2015. However the local Sanofi team that operated in the area still had a relationship with him/her as a *bona fide* NHS customer. However, since March 2015, Sanofi had not contracted any services including nurse-led clinics, clinical audits or training events from him/her or his/her company.

Sanofi submitted that whilst it worked with the training and consultancy company, the relationship between it and the named health professional was managed through the local Sanofi NHS outcome manager (NOM). The NOM would hold a non-promotional discussion with the relevant stakeholders in the local healthcare practices to determine whether there was an unmet need to improve the management of the specific condition in their respective practices. If a particular unmet need was identified, the NOM would complete a referral form to provide key contact details for the practice. This referral for the specialist nurse team programme was then sent to the Sanofi medical manager in head office for review and approval. If considered eligible for the MEGS service, the medical manager would ask the named health professional/the training and consultancy company to contact the relevant practice directly to discuss the nurse-led service in detail. If the practice agreed to participate with the nurse-led service run by the training and consultancy company, then an honorary nurse agreement would be issued and signed by the health professional at the practice and by the named health professional. Once the agreement had been set up the NOM would play no further role in any discussions about the nurse review service at that practice.

Sanofi did not normally track sales against the placement of MEGS programmes. However, as a result of this case, it confirmed that there was no evidence which linked the deployment of the nurse team programme to a disproportionate increase in the sales of relevant Sanofi products. To help validate this Sanofi provided sales growth month by month graphs for September 2013 to December 2015 for the two relevant products which it actively promoted when it supported the training and consultancy company nurse-run service. Each graph illustrated a month by month sales line for the respective product from both a UK perspective and from the three CCGs that received the training and consultancy company service. The graphs illustrated that local sales of those products during November 2013 to February 2015 were overall not markedly dissimilar to that of the UK average sales month by month trend; thus one could surmise that the training and consultancy company nurse service run at the time did not directly impact on the uptake of Sanofi products in those practices that received it.

Sanofi refuted that the nurse-led service that was supported with the training and consultancy company breached the Code and in particular Clauses 2, 9.1, 18.1, 19.1, 19.2, 21 and 23.1 as alleged.

In response to a request for further information regarding its relationship with the training and consultancy company, Sanofi stated that it had attempted to respond with as much information as possible which it held relating to its prior relationship with the training and consultancy company. However, it was unable to supply all the information requested by the Authority as this was a local project within a limited geography, which was set up over 3 years and was run by Sanofi employees who no longer worked for the company. Sanofi had therefore not been able to fully investigate this case because some employees

who were involved were no longer with the company and so could not be interviewed.

The practices which received the training and consultancy company run patient management and nurse advisor service between 2014 and 2015 were based in a particular region. These practices and community clinics were within the three CCGs. Sanofi provided a list of practices and community hospital clinics which received the service from the training and consultancy company.

The NOM employed by Sanofi at the time, was first approached by the named health professional in late 2013 offering the services that his/her training and consultancy company could provide to local primary care and community-based hospital clinics. The training and consultancy company proposal was shared with the head office medical team and it was agreed to commence a pilot project with the training and consultancy company which led to the first contract being created at the end of 2013. No other providers of such services were approached by Sanofi for consideration at that time for this locality.

The NOM at the time would conduct a non-promotional discussion with the relevant stakeholders in the local healthcare practices to determine whether there was an unmet need to improve the management of relevant patients in their respective practices. The NOM followed guidance to only select suitable practices for a discussion on the potential healthcare benefits that the service could provide. As outlined in the document, the service was to only be offered to those healthcare organisations which met the following criteria:

- The individual healthcare organisation must be actively involved in the management of patients with the particular condition
- The health outcomes of patients in the area serviced by the individual healthcare organisation must be 'poor' according to national tools and criteria
- The individual healthcare organisation must be at least a 3-partner medical practice with 5,000 patients; and must be able to identify sufficient patients requiring improved clinical management.

Where the individual healthcare organisation met these criteria, the service was to be offered unrestricted upon request following a discussion with the responsible NOM. The NOM was to thus discuss with the practice such factors as the local prevalence of the condition in the community, whether the practice had hit population targets for control in these patients and how the practice managed its patients such as having specialised clinics for reviewing such patients, etc. If a particular unmet need was identified, the NOM would complete a referral form to provide key contact details for the practice which was then sent to the Sanofi medical manager in head office for review and approval as described above.

No further correspondence was available regarding whether the training and consultancy company made any recommendations in this regard.

Every quarter, the named health professional/the training and consultancy company would send Sanofi a progress report detailing which practices had received its nurse-led service and how many clinics had been delivered by its nurse team at the respective clinics. An example of such a report was provided. As indicated in the service operating procedure, no information regarding the performance of the service was provided apart from the above and no patient level information was shared at such meetings.

The representatives were not involved in the training and consultancy company service apart from the one NOM employee who no longer worked for Sanofi. Sanofi believed that the NOM verbally briefed the local representatives at the time that the service was available to those practices that expressed an interest for the services offered by the training and consultancy company. However, the representatives played no active part in any communication regarding the training and consultancy company services in their practices. There was no documentary evidence about these local discussions between the sales team and the NOM from this time. According to Sanofi's customer relations management (CRM) record system, the named health professional saw its representatives during the time that the training and consultancy company nurse advisor service ran in 2014. Sanofi recorded 14 separate representative visits to the named health professional during this time period which included the one non-promotional strategic discussion with the NOM to discuss the training and consultancy company nurse advisor service. According to Sanofi's CRM records, it did not believe that the other promotional calls made by the representatives with the named health professional discussed the training and consultancy company nurse advisor service.

At the beginning of 2015, Sanofi determined that a nurse-led service was a valuable resource to the NHS nationally and not just within a small region. Hence it was decided to expand the nurse-led service using a provider with a solid reputation and the governance capabilities and resources to run a nationwide service. Therefore, Sanofi decided to create an upgraded nurse-led service using another healthcare organisation to provide the expertise and nursing resource across the country and so the contract with the named health professional and the training and consultancy company was terminated. There was no specific ban but rather there was no need for Sanofi to continue to work with the training and consultancy company locally considering that a replacement service was fully developed and was to be available nationwide.

Sanofi confirmed that from March 2015 it had not worked with the training and consultancy company or carried out any form of activity at exhibition stands in meetings that it had run.

PANEL RULING

The Panel noted that the anonymous complainant was non contactable and so could not be asked to

provide further details. Anonymous complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence in support of the allegations.

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

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

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

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

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

In addition, the Panel noted the case preparation manager's advice that matters would generally be considered in relation to the requirements of the Code applicable when the matters at issue occurred.

The Panel noted Sanofi had only worked with the training and consultancy company to provide a patient management and nurse advisor service. The Panel noted that according to the Patient Management Service Operating Procedure the service was a medical and educational good and service (MEGS) which included a review of patients' current treatment regimen in line with locally agreed guidance. The service ran from early 2014 until 28 February 2015. The relevant requirements for MEGS in the 2014 Code (Clause 18.4), and the 2016 Code (Clause 19.1) were identical. The last two months that the service was offered was within the transition period for the 2015 Code and so that Code did not apply. In addition the Panel noted that the training and consultancy company delivered the MEGS service on behalf of Sanofi as set out in a series of contracts. Such contractual arrangements were covered by Clause 18.7 of the 2014 Code and these relevant requirements were now reproduced in Clause 21 of the 2016 Code. The Panel thus made its rulings under the 2016 Code.

In relation to clinical audits, the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product, little consideration was given to other therapies, and surgeries exhibited irregular use of a sponsor's product. The Panel noted the requirements of the Code set out in Clauses 18 and 19 and the supplementary information to Clause 19.1 Switch and Therapy Review Programmes. The relevant supplementary information stated that Clauses 18.1 and 19.1 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a company's medicine is simply changed to another. It was acceptable for a company to promote a simple switch from one product to another but not to assist the health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. A therapeutic review was different to a switch service: it aimed to ensure that patients received optimal treatment following a clinical assessment and was a legitimate activity for a pharmaceutical company to support and/or assist. Clause 19.2 stated that medical and educational

goods and services in the form of donations, grants and benefits in kind to institutions, organisations and associations that were, *inter alia*, comprised of health professionals or provided healthcare were only allowed if they complied with Clause 19.1, were documented and kept on record by the company and did not constitute an inducement to prescribe.

The Panel noted that although the named health professional originally requested the service and that it be delivered by his/her training and consultancy company, the service was described in the consultancy services agreements with the training and consultancy company as a service to medicine developed by Sanofi. Sanofi was thus responsible under the Code for it. The agreements stated that the role of the training and consultancy company was to deliver the service and undertake patient assessment clinics.

The Panel noted that according to the service operating procedure the service was to be offered, unrestricted, to local practices upon health care provider request by an NHS outcome manager (NOM) if the practice satisfied the criteria set out in the service operating procedure; namely the size of the practice, its active management of patients with the condition, the health outcomes of relevant patients in the area serviced by the practice must be poor as defined by national tools and finally the practice must be able to identify sufficient patients who needed improvement. If the NOM was satisfied that these criteria were met a Sanofi medical manager would then contact the named health professional who would then deliver the service as set out in the service operating procedure via his/her training and consultancy company.

The Panel noted that his/her objective of the service was to help relevant patients effectively improve control of their condition and reduce their risk of complications. According to the service operating procedure, specialist nurses employed by the training and consultancy company, or the named health professional him/herself, individually assessed patients and reviewed their treatment in line with locally agreed guidance provided by the practice so that there was clarity on treatment. The locally agreed guidance would include national guidance/treatment pathways. An agreement between the training and consultancy company and each individual practice provided that 'the practice would at all times retain clinical responsibility for the management of patients under its care including but without limitation all prescribing decisions and patient management'.

The Panel noted Sanofi's submission that local sales data showed that the service did not directly affect the uptake of Sanofi products in those practices that received the service. Taking all the circumstances into account the Panel considered that the complainant had not established that the provision and operation of the diabetes management and nurse advisor service was an inducement to prescribe or otherwise contrary to the Code as alleged. No breach of Clauses 18.1, 19.1 and 21 of the Code was ruled. High standards had been maintained. No breach of Clause 9.1 was ruled. Nor had the complainant established a breach of Clause 2; no breach of that clause was ruled.

The Panel noted that Sanofi had also been asked to respond to the requirements of Clauses 19.2 and 23.1 of the 2016 Code. There was no evidence before the Panel that Sanofi had engaged in any relevant activities. The Panel ruled no breach of Clauses 19.2 and 23.1 accordingly.

During its consideration of this case, the Panel was concerned to note Sanofi's submission that during 2014 it had recorded 14 separate representative visits with the named health professional, 13 of which it implied were promotional calls. The Panel queried whether such visits complied with Clause 15.4 of the Code. The supplementary information to that clause stated that on average, the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed 3. The Panel noted that the meetings took place at different healthcare venues. The Panel requested that the company be advised of its views.

Complaint received **3 August 2016**

Case completed **19 December 2016**