

ANONYMOUS, NON CONTACTABLE v TAKEDA

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 Takeda. 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. Reference was made to Takeda's product. 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 Takeda's is given below.

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

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

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

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

In relation to the audits in a named CCG the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product with little consideration given to other therapies and that surgeries exhibited irregular use of a sponsor's product. Reference was made to abnormally high sales of Takeda's product. The Panel noted the relevant requirements of the Code about switch and therapy review programmes.

The Panel noted Takeda's submission that when it received the complaint it did not know of any funds provided to the named health professional or the training and consultancy company for audits but during the investigation of the complaint it

became aware that the named health professional had delivered two therapy reviews commissioned by clinicians who had received support for those reviews from Takeda in 2015. The Panel noted that Takeda had made a grant to large health centre to run nurse clinics at 11 local practices. Another grant was paid for a similar nurse led clinic at a medical centre based within a different CCG.

The grant request from the medical centre explained that it would work with a company it had previously worked with to deliver the clinics; the company was not named. The service provider and its status was not identified in any of the materials for the medical centre. The Panel noted that according to Takeda in each case the practice had initially raised its need for funding with either the representative and/or his/her line manager who each advised that an application be made to the company.

The Panel did not accept that Takeda only found out that the named health professional and the training and consultancy company were involved with the audits when it investigated this complaint. Indeed the Panel noted that in relation to the review at the medical centre Takeda paid the monies in October 2015 directly to the training and consultancy company rather than the medical centre. In the Panel's view, at the latest, either on payment to the training and consultancy company (in relation to the medical centre) or when the therapy reviews were taking place, individuals at Takeda were aware of the involvement of the training and consultancy company.

Takeda had stated that it could not comment on any correlation between the training and consultancy company activity and prescribing but noted that its product's use was significant within one of the CCGs where the therapy review took place before the grant request and that the medicine was by a significant margin the least expensive in its class available in the UK.

The Panel first had to consider Takeda's responsibility for the audits. Noting the level of contact between the parties, previous discussions about the need for audits and advice from field-based staff to apply for funding the Panel queried the company's submission that the funding requests were unsolicited. The Panel noted the grant agreements for each therapy review stated that the grant was not an inducement to, or reward for recommending or taking any decisions favourable to Takeda's products or services. The agreements also referred to the NHS body providing a brief report to Takeda on request or as agreed by the parties. The accompanying letters to the practices, however, stated only that Takeda would be extremely interested to hear about the outcomes but that the NHS body was not obliged to provide such details. In addition, the agreement for the health centre stated that it was fully responsible for all aspects of the event; there was no similar statement in the agreement with the medical centre.

The Panel considered that on the available evidence neither audit was a Takeda activity and thus the clause of the Code that applied to the provision of medical and educational goods and services provided by the company did not apply. No breach of the Code was ruled. The Panel noted that the Code described the circumstances in which a medical and educational good and service could be provided as a donation, grant or benefit in kind. The Panel considered that it was beholden on the company to undertake due diligence when making a restricted use grant for a therapy review to a GP practice or group of practices. This was especially important when the restricted use grant was for an audit in an area where the company had a commercial interest. Such due diligence should ensure, *inter alia*, that the arrangements were not and could not be perceived as an inducement to prescribe.

Whilst the Panel had concerns about Takeda's governance of the restricted use grants it nonetheless noted that the complainant bore the burden of proof. The Panel did not consider that the complainant had established that provision of funds and/or the arrangements for the therapy reviews were such that they were a switch service or otherwise an inducement to prescribe as alleged. No breach was ruled.

The Panel noted that Takeda paid for an exhibition stand at a one day clinical awareness course run by the training and consultancy company. Other companies also exhibited. The Panel noted that an email regarding sponsorship from representative 1 to representative 2 referred to the named health professional doing extra clinics in certain cases and helping and supporting representative 1 with [Takeda's product] in a named area by 'convincing GP practices to switch and use the [Takeda's product] family'. The meeting at issue was referred to as one which the named health professional had asked the representatives to support and 'in return [the named health profession] has agreed that he/she will advocate, and help and support us in our cause in primary care with the [Takeda's product] family'. Representative 2 was asked to contact the named health professional. The email in question was copied to the representatives' line manager and the direct report of representative 1, a primary care representative. The Panel noted Takeda's submission that the senior line manager asked representative 1 to refer the proposal to a senior director but failed to recognise that the email suggested a link between the provision of funding and advocacy and support for Takeda's product. Takeda had not stated whether the senior director saw the original email and, if so, what he/she did with the email or who sanctioned the payment. The representatives gave differing accounts of a subsequent meeting with the named health professional to discuss funding of the course at issue. Representative 1 stated that the named health professional made it clear that he/she would advocate Takeda's product in return for funding. This was denied by representative 2. A customer relations management (CRM) report for a subsequent meeting with the named health

professional stated that he/she agreed to help via speaker meetings to endorse Takeda's product across the region. The Panel also noted Takeda's submission that when it paid for the exhibition stand space, it did not take adequate steps to ensure that it did not exceed fair market value. The Panel considered that given the link between funding and support for Takeda's product as stated in the email, the payment was contrary to the Code and breaches were ruled. The company had failed to maintain high standards and a further breach was ruled.

The Panel was very concerned that despite the senior line manager being copied into the email in question no steps were taken by senior staff to review the initial arrangements or otherwise prevent payment. The level of payment was not assessed to make sure it did not exceed fair market value. In addition, the Panel noted that an inducement to prescribe was listed in the supplementary information to Clause 2 as an example of an activity likely to lead to a breach of the Code. The Panel considered that the impression created by the email brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its rulings of breaches of the Code in relation to the arrangements and impression created by the email. The Panel considered all the circumstances surrounding the meeting with the named health professional very carefully including that the representatives gave differing accounts of that meeting. The Panel also noted that a ruling of a breach of Clause 2 would be the subject of an advertisement in the medical, pharmacy and nursing press. Taking all the circumstances into account, and on balance, the Panel decided not to report Takeda to the Code of Practice Appeal Board on this point for it to consider whether further sanctions were warranted.

The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that the engagement of the named health professional to speak at the two promotional meetings in 2015 was an inducement to prescribe. No breach of the Code was ruled. Nonetheless, the Panel considered that his/her contemporaneous engagement in non-promotional and promotional roles either personally or via the training and consultancy company was not compatible. It did not appear that the company had undertaken any due diligence in this regard. High standards had not been maintained and a breach of the Code was ruled.

The Panel noted that Takeda had also been asked to respond to the requirements of the Code about relationships and contracts with certain organisations: there was no evidence before the Panel that Takeda had engaged in any such activity and thus no breach 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 Takeda Limited.

COMPLAINT

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

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

The complainant explained that the training and consultancy company had conducted industry funded 'clinical audits' in several surgeries across a named part of a city, those practices were very easy for medicines management to identify as they had highly irregular use of the sponsor's product. In several surgeries in a named CCG patients were either initiated onto or switched to the sponsors' medicine with little consideration given to alternative therapies. This situation was particularly obvious when sales data for Takeda's product were assessed. In a named area there was a remarkable correlation between strong product sales and surgeries that had received the training and consultancy company support funded by Takeda. The product was only added to the relevant local formulary in November 2015, yet sales in these surgeries were abnormally high throughout 2015. 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 a 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 Takeda, 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

Takeda submitted that as a member of the ABPI it strove to abide by the letter and spirit of the Code and maintain high standards in its activities at all times.

Takeda submitted that it had had a number of interactions with the named health professional in his/her capacity as both a health professional and a provider of educational services. Since April 2013 Takeda had knowingly engaged him/her on a fee for service basis on five occasions; Takeda stated the total transfer of value involved.

Takeda submitted that with regard to involvement in audit activity in the relevant area, when it received the complaint it had no knowledge of any funds provided to the named health professional or the training and consultancy company. However, in the course of investigating this complaint Takeda submitted that it had become apparent that the named health professional delivered two therapy review services commissioned by clinicians who had been given donations from Takeda.

Takeda submitted the following information with regard to interactions with the named health professional/the training and consultancy company, including the therapy reviews funded via donations:

- Purchase of exhibition stand space at a training and consultancy company educational meeting, 2014
- Various interactions between Takeda representatives and the named health professional in his/her capacity as a health professional
- The named health professional engaged as a consultant speaker at two Takeda internal training days in 2015
- The named health professional engaged as a consultant speaker at two promotional meetings at two GP practices in 2015. Both practices were in the CCG in which the complainant stated that the health professional had prescribing responsibility
- Request for donation made by the training and consultancy company to fund provision of clinics – declined
- Two therapy reviews indirectly funded by Takeda at two named medical centres in two different CCGs in 2015.

Purchase of exhibition stand space at a the training and consultancy company educational meeting, 2014

Takeda submitted that it paid for a promotional stand at this one-day educational meeting aimed at nurses and healthcare assistants and organised by the training and consultancy company. Takeda's detailed comments about this sponsorship appear below.

Various interactions between Takeda representatives and the named health professional in his capacity as a health professional

Takeda's representatives met with the named health professional on a number of occasions between 2014 and 2016; he/she was an experienced clinician and regarded by Takeda's representatives as a local key opinion leader in specific field. The named health professional worked at a number of local GP practices and therefore was present at a number of sales visits made by the company's representatives. As a regular prescriber of medicines the named health professional was invited along with other health professionals to various promotional events. No fees were paid for any of these activities. All interactions with the named health professional recorded on Takeda's customer relationship management (CRM) system were provided.

Two internal training days in 2015

The named health professional was contracted by Takeda to provide training in the management of a condition at an internal training course for representatives with variable levels of knowledge in the therapeutic area. Payment details were provided which, in Takeda's opinion, represented fair market value for a specialist nurse and were in line with the company's standard rates. The named health professional delivered a PowerPoint presentation certified by Takeda signatories. Takeda considered these engagements a legitimate use of the named health professional's services as a consultant.

Promotional meeting, GP practice, November 2015

The named health professional's services as an expert practitioner were contracted by Takeda for a lunchtime promotional meeting at a GP practice, to discuss the use of its products in suitable patients. The presentation used certified Takeda slide decks. The named health professional was contracted for three hours work including two hours preparation and one hour training. Takeda considered this engagement a legitimate use of the named health professional's services as a consultant.

Promotional meeting, GP practice, December 2015

The named health professional's services as an expert practitioner were contracted by Takeda for a lunchtime meeting at a GP practice, to discuss case studies and recently updated guidelines from the National Institute for Health and Clinical Excellence (NICE). The named health professional's presentation used certified Takeda slide decks. The named health professional was contracted for one and a half hours' work including one hour presentation and half an hour preparation. Takeda considered this engagement a legitimate use of the named health professional's services as a consultant.

Background to Takeda's donations to support therapy review and audit activities

All requests to Takeda for financial support were reviewed by a Grants and Donations Committee, which comprised members of both medical and compliance departments, in accordance with Takeda's standard operating procedures (SOPs). Only unsolicited requests for funding were considered and the judgement of whether an application for financial support was approvable rested entirely with the committee. Takeda stated that all successful requests for funding must be from an institution or organisation and substantiated by a written description of the use to which the requested funds would be applied. The committee took no account of matters concerning the prescribing, purchasing or reimbursement of any Takeda medicine when considering an application. Uplift in sales of any Takeda product following a grant was not monitored.

To avoid creating misplaced perception that funding decisions were contingent on the use of Takeda's medicines, Takeda had previously considered grant requests on the basis of the information provided by the applicant and had not routinely asked for further specific information to be provided. Since the appointment of new senior directors in late 2015, the process had changed to include a greater degree of due diligence. The committee now frequently asked applicants for further information to ensure that grants and donations were only made to support activities with which the company was entirely comfortable.

Request from the training and consultancy company for a donation to fund provision of clinics – declined

In 2014 the named health professional's application for a donation on behalf of the training and

consultancy company to provide fifty clinics in the named area was reviewed and declined by the Grants and Donations Committee.

Therapy review indirectly funded by Takeda at a health centre, 2015

The Grants and Donations Committee received a letter from a GP at a health centre in 2015 requesting funding for clinics in a specified therapeutic area at various local practices. The clinics would be run by specialist nurses in conjunction with local GPs. The health centre stated a local disease prevalence of 9% and aimed to provide the additional clinics to improve the quality of care for these patients. The application did not specify which individual(s) or company would be providing the service. This application was reviewed and approved by Takeda. As per the contractual agreement between Takeda and the health centre, each party acknowledged and agreed that 'the agreement is concluded independently from any business transactions and decisions in relation to the supply or purchase of goods and services from Takeda ... and that the provision of the contribution shall not in any way: (i) constitute any inducement to, or reward for, recommending or taking any decisions favourable to any products or service of Takeda ...'. Takeda believed that this donation was appropriately reviewed and approved and provided in good faith with the intention of improving patient care. Whilst investigating this complaint, Takeda now understood that the health centre engaged the named health professional to undertake these clinics.

Therapy review indirectly funded by Takeda at a medical centre, 2015

Takeda's committee received a letter requesting funding for additional clinics at a different medical centre. The centre applied for funds to run three weekly surgeries over 26 weeks, including administration costs. The aim was to improve control of the disease in its locality. The application letter did not indicate which individual(s) or company would provide this service, it only stated that it was intended to commission the service from independent specialist nurses. The application was reviewed by the committee on 14 July 2015 and it decided to contribute one third of the sum requested towards the service. As per the contractual agreement between Takeda and the medical centre, each party acknowledged and agreed that 'the agreement is concluded independently from any business transactions and decisions in relation to the supply or purchase of goods and services from Takeda ... and that the provision of the contribution shall not in any way: (i) constitute any inducement to, or reward for, recommending or taking any decisions favourable to any products or service of Takeda ...'. Takeda believed that this donation was appropriately reviewed and approved and provided in good faith with the intention of improving care for relevant patients. During the course of investigating this complaint, Takeda now understood that the health centre had engaged the named health professional to undertake these clinics.

Takeda denied breaches of the Code in relation to the speaker engagements and grants.

Takeda subsequently submitted that whilst initially investigating this complaint and its sponsorship of an educational meeting in 2014, an email was passed to a senior director which gave cause for concern and resulted in further investigation. Though these investigations were ongoing, Takeda was now able to fully respond to this complaint regarding interactions with the named health professional.

Purchase of exhibition stand space at a the training and consultancy company educational meeting, 2014

Takeda submitted that an email was sent by one regional account director (representative 1) to a colleague (representative 2), copying in their line manager and the direct report of representative 1 (primary care representative). The email alerted representative 2 to the presence of the named health professional as a respected specialist nurse operating across the territories of the two representatives and discussed providing financial support for an awareness course being run by the named health professional. However, the wording of the email raised concerns, specifically:

- '[the named health professional] is ... helping and supporting me with [Takeda's product in a named area] i.e. convincing GP practices to switch and use the [product] family.'
- 'In return [for providing financial support for a course being run by the named health professional he/she] has agreed to advocate, and help and support us in our cause in primary care with the [product] family.'

Representative 1 explained that he/she had written the email a few weeks after starting work in the field with Takeda and was, to some extent, showing off to both representative 2 and his/her line manager by overstating the extent of his/her relationship with the named health professional. Representative 1 also stated that when he/she wrote the email, the named health professional had never indicated that he/she would advocate or in any other way support [product] in return for any kind of financial support.

Takeda submitted that representatives 1 and 2 met the named health professional one week after the email was sent, to introduce him/her to representative 2 and to discuss Takeda potentially funding the awareness course which the named health professional was due to run a few days later. The representatives' account of that meeting differed. Representative 1 claimed that the named health professional made it clear that he/she would advocate Takeda's product in exchange for Takeda supporting the awareness course. Representative 2 stated that no such discussion took place and that discussions regarding the course focussed on the educational/scientific value of the course and the mechanisms by which Takeda could fund the course. No minutes of the meeting were available.

Takeda submitted that after meeting with the named health professional, representative 2 committed to procuring stand space at the awareness course meeting which took place in October and the training and consultancy company was subsequently paid. Representative 2 made clear that he/she sponsored this event with the legitimate intent of discussing Takeda's product and developing relationships with primary care specialist nurses, which was a key business tactic at that time. Representative 2 admitted to not giving due consideration as to whether the amount paid for the stand space represented fair value given the scale of the meeting, but agreed to this sum partly on the basis that he/she understood that a competitor had paid the same for a stand at the meeting.

Representative 2 confirmed that the stand was erected in a separate room from the course itself and expressed disappointment that the event attracted only approximately 20 nurses; he/she had expected 30-40 to attend. Following this meeting, representative 2 did not support any further courses arranged by the named health professional/the training and consultancy company.

Meetings with the named health professional in restaurants

As part of the investigation of this complaint, interactions between Takeda personnel and the named health professional were identified from the CRM system. Nine meetings took place in restaurants, including promotional meetings where the named health professional was one of a number of delegates and a 1:1 meeting between the named health professional and the primary care representative. These meetings were all investigated and it was found that:

- Venues were all appropriate for meetings with health professionals
- Amounts paid for subsistence were reasonable and fell within both the £75 limit stipulated by the PMCPA and stricter limits imposed by Takeda's SOPs
- Private rooms were used for promotional meetings, though this was not consistently documented within the CRM system
- Agendas were not available for all promotional meetings, therefore it was not possible to verify that there was always sufficient educational content to justify the provision of food
- Minutes of 1:1 meetings were not kept. However, following interviews with the representatives Takeda believed that these lunchtime meetings incorporated substantial business-related discussions.

Summary

Takeda submitted that given, at times, conflicting accounts from different representatives and a lack of contemporaneous written records of particular meetings, it was not possible to tell whether certain clauses had been breached. However, based on the information available, there appeared to have been breaches of Clauses 9.1, 18.1, 23.1 and 22.1. Takeda denied breaches of Clauses 2, 19.1, 19.2 and 21.

Takeda was disappointed with some of the findings which had arisen from the investigation of this complaint. It had become clear that a number of processes and controls pertaining to the management of the field force required reinforcing. A detailed internal audit of field force activities would be initiated. Once the internal investigation of this complaint was concluded, appropriate disciplinary action would commence.

Takeda remained committed to abiding by both the word and spirit of the Code at all times.

In response to a request for further information, Takeda provided the following:

Product review taking place in a particular geographical area

This reference in the CRM system was to a review of the prescribing of a class of products being undertaken by the local area prescribing committee which operated across 5 CCGs. Takeda was not involved either directly or indirectly with this review. Furthermore, Takeda did not know whether the named health professional was involved in this review. The representative met with the named health professional in his/her capacity as a contracted specialist nurse at a community hospital. The comment made about the ongoing prescribing review simply represented the recording of an important insight which might impact Takeda's business.

Application for donation by the training and consultancy company

The application for funding of therapy reviews was rejected by Takeda since it was submitted by a commercial organisation. Takeda had historically funded grant requests for therapy reviews submitted by NHS bodies, but not by private companies.

The regional account director who covered the relevant geographical area had stated that he/she was not aware of this grant request. Takeda had no reason to believe that this request was discussed with any other members of the sales force.

Named GP Practice

Takeda did not undertake or fund any therapy review at this practice. The representative's comments on the CRM system referred to a review the practice was undertaking, which was evidently being conducted by the named health professional in his/her capacity as a specialist nurse working there.

Clause 19

Takeda was fully aware of the requirements of Clause 19 relating to the provision of therapy review services. As previously described, the therapy reviews referred to above were not supported by Takeda. Therefore CRM entries related to these reviews simply represented the recording of important business insights which might impact Takeda's business. As stated above, Takeda had no reason to believe the grant request from the training

and consultancy company was discussed with any member of the sales force.

Takeda therefore did not believe that Clause 19 had been breached in relation to any of these therapy reviews.

Health centre

During the course of Takeda's investigation, two regional account directors and a representative, who took part in meetings with a GP and the named health professional, were interviewed. Takeda's response was based on these interviews as well as a review of relevant records.

The meeting with the GP at the health centre in March 2015 was a promotional call by the representative to discuss the benefits of a product, specifically in relation to price. No therapy review activities were discussed. The named health professional was at this meeting in his/her capacity as a contract specialist nurse working with the GP.

The meeting in April with the named health professional at a hospital again involved the same representative and discussed the way in which patients at the health centre had their therapy optimised. The representative maintained that potential Takeda-supported therapy reviews were not discussed during this meeting.

The representative stated that he/she separately received a telephone call from the health centre requesting financial support for an audit programme intended to improve the management of patients in a particular therapeutic area across a number of local practices. Specifically, performance in respect of the key processes of care for patients had now apparently fallen well behind NHS performance targets which had resulted in suboptimal care. The representative maintained that he/she advised that it would need to apply for a grant via Takeda's grants and donations process. The representative had no subsequent involvement in this grant application. On the basis of the investigation which had taken place, Takeda believed this grant request was unsolicited. During the course of the investigation, no correspondence which might have prompted the health centre to submit a grant request had been identified.

Once the grant had been made and the audit programme was in operation, the representative became aware that the programme was supported by a grant from Takeda and that the named health professional had been engaged to undertake the audit. He/she could not recall the exact date on which he/she became aware of this.

In the spirit of transparency, Takeda was keen to ensure that whenever a grant or donation was made to support a particular service, this was made clear to relevant parties, including patients who were invited to participate in that service. Therefore, letters sent out to inform applicants that their grant request had been approved included the following: 'We must therefore ask that any material produced in relation to this project contains a prominent declaration

stating the nature of the involvement of Takeda UK and that all participants and beneficiaries of the project being supported by the grant are aware of the involvement of Takeda UK'.

When this grant was made, Takeda evaluated grants requested based solely on the information provided by the applicant in his/her application. This was due to a concern that undertaking further due diligence could create the erroneous impression that Takeda looked to evaluate the impact of potential projects on the prescribing of its medicines before it decided whether to approve grant requests. The appointment of new medical and compliance staff had resulted in a change of approach. The Grants and Donations Committee now defined due diligence steps which must be taken in respect of each approved grant, based on factors including the amount requested, the type of applicant (eg GP practice/NHS trust/ individual clinician) and the nature of the request.

The Grants and Donations Committee was responsible for determining whether a particular grant application was approvable based on Takeda's relevant SOP and the Code. Whether or not an 'approvable' grant request could be fulfilled then depended on the availability of sufficient budget within the business. The brand director identified budget to support this request but as he/she had now left the business, Takeda ascertained the factors he/she took into account in deciding to allocate budget to support this request.

Complainant's allegation about a named CCG

Takeda noted the complainant's allegation in relation to the 'sponsor's medicine', which went on to reference its product specifically. The health centre's request for a grant to support a local audit to focus on 'optimising treatment' did not refer to any specific medicine or class of medicines. As described above, Takeda did not request any further information regarding the audit beyond that submitted by the health centre and therefore remained unaware of whatever protocol or guidelines were used to determine any medication changes. Takeda strongly refuted any suggestion that this grant was made with either the expectation or intention of increasing local sales of its product.

Complainant's assertion about a correlation between product sales and sponsored activity

Takeda could not comment on the assertion regarding 'correlation' between the training and consultancy company activity and prescribing of Takeda's product without seeing the data on which the assertion was based. However, it was important to note that use of Takeda's product was significant within the local CCG area before the grant request was received.

In order to provide further context, Takeda stated that its product was supported by an extremely robust value proposition. It was, by a significant margin, the least expensive product in its class available in the UK. This had resulted in strong sales growth across the UK.

Medical centre

During the course of Takeda's investigation of this complaint, the representative responsible for this practice was interviewed. Takeda's response was based on this interview as well as a review of relevant records. A meeting in March 2015 at the medical centre was a small group promotional meeting which discussed improving patient outcomes. Takeda's records indicated that the GP who applied for the grant, the named health professional and two other health professionals attended.

The GP stated during the course of the meeting that he/she would like to engage an independent provider to undertake a therapy review across 3 different practices. He/she was particularly keen to ensure that uncontrolled patients were identified and offered step-up therapy and that newly diagnosed patients were initiated on appropriate treatment. The GP did not identify which provider he/she would look to commission and the representative did not know that it would be the named health professional.

In respect of the proposed therapy review project, the representative referred the GP to his/her line manager who then advised the local GP to apply for funds via the grants and donations process. Neither the representative nor his/her line manager were subsequently involved in this grant application. On the basis of the investigation which had taken place, Takeda believed that this grant request was unsolicited. During the course of the investigation, no correspondence which might have prompted the local GP to submit a grant request had been identified.

Once the grant had been made and the therapy review project was in operation, the representative found out that the review had been supported by a grant from Takeda and that the named health professional had been engaged to undertake the review. He/she could not recall the exact date on which she became aware of this.

As stated above, when this grant was made, Takeda did not undertake due diligence activities with respect to unsolicited requests for grants and donations beyond reviewing materials submitted by the applicant.

The Grants and Donations Committee deemed this grant request to be approvable and so it was necessary to identify whether funds were available to support it. In this instance, the medical team identified funds to partially support this request. A grant of one third of that requested was ultimately approved.

SOPs and Guidance

Takeda provided relevant SOPs and guidance.

Sponsorship of the exhibition stand, 2014

When the senior line manager, who was copied in on this email, received it he/she asked the regional account director to refer the proposal that Takeda fund the attendance of practice nurses at the

awareness course to a director. Unfortunately, he/she failed to identify that the email also suggested a link between the provision of funding for the awareness course and advocacy and support for Takeda's product by the named health professional. He/she therefore took no further follow-up action. Takeda believed that this omission represented a failure of oversight and it would take appropriate steps with this individual.

The direct report of the regional account director who wrote this email did not recall having actually read this email when it was sent.

Representative 1, who drafted the email, was relatively new to Takeda and had based his/her statements about how to sponsor nurses to attend the awareness course (incorrectly) on his/her understanding of a previous employer's policy. The assertion that 'we cannot sponsor nurses to attend educational events' was not correct, although an individual representative was not empowered to provide such support.

Takeda supported individual health professionals to attend relevant educational meetings either proactively (eg where the medical department selected individuals to invite to attend a major congress) or reactively, where an individual submitted an unsolicited request for support to attend a particular educational meeting or congress. Representatives were not involved in the decision making process in either scenario.

With the exception of major congresses which Takeda proactively invited health professionals to attend, Takeda did not pay delegate fees to meeting organisers, such as the training and consultancy company. When a health professional approached Takeda to request support to attend a meeting such as the awareness course, they were advised to apply via the Grants and Donations process. If, upon review, the Grants and Donations Committee approved the application, then the health professional was asked to provide confirmation from the meeting organiser that his/her registration had, in fact, been paid. Takeda then reimbursed the health professional's institution (eg NHS trust/university).

The monies which had been paid to the named health professional/the training and consultancy company had not caused concern until this email was brought to Takeda's attention during investigation of this complaint. All other payments made to the named health professional/the training and consultancy company had been reviewed during the course of this investigation and were felt to be appropriate.

This payment for the exhibition stand was approved by a line manager; relevant supporting documentation was provided. When this payment was made, adequate steps to ensure that it did not exceed fair market value were not taken. Given that information relevant to making a fair market value assessment, such as number and expertise of speakers involved in delivering the meeting and the number of delegates attending, was not captured, it was not possible to make a fair market value assessment retrospectively.

Takeda could not therefore determine whether this payment represented fair market value. Takeda recognised that whilst this payment was approved in line with its existing policies, greater scrutiny should be applied to the sponsorship of exhibition stands. As a result of this complaint and subsequent investigation, a number of SOP revisions would be made. These would include the requirement for greater scrutiny in this area.

Pressure to select the named health professional as a speaker

Based on Takeda's investigation, including interviews with representatives in the areas in which the named health professional worked, there was no evidence that any of them had felt pressurised to use him/her.

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 Takeda, 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. Takeda had, however, responded to all matters raised in the complaint and the Panel ruled accordingly. The Panel considered that the scope of the complaint included the engagement of the named health professional and/or the training and consultancy company activities, with health professionals, whether such activities were delivered by its owner, the named health professional or other individuals. However, when considering such matters the totality of a company's interactions with the named health professional would, nonetheless, be relevant.

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

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

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

The Panel noted that Takeda's provision of restricted use grants for therapy reviews to two GP practices and the engagement of the named health professional as a speaker at promotional meetings occurred during 2015. There were no significant differences between the relevant requirements of the 2015 and the current 2016 Code and thus these matters were considered under the 2016 Code. The Panel noted that Takeda had sponsored a training and consultancy company meeting in October 2014 by purchasing space for an exhibition stand. The Panel noted that there was a difference between the 2014 and 2016 Codes in the supplementary information to Clause 2 in that the supplementary information to the 2016 Code gave 'unacceptable payments' as an example of a breach of Clause 2. This difference was potentially relevant to the matter at issue and thus all matters pertaining to the October 2014 meeting were ruled under the requirements of the 2014 Code.

In relation to the audits in a named CCG the Panel noted the allegation that patients were either initiated or switched onto the sponsor's product with little consideration given to other therapies and that surgeries exhibited irregular use of a sponsor's product. Reference was made to abnormally high sales of Takeda's product. The Panel noted the

requirements of the 2016 Code set out in Clauses 18 and 19 and the supplementary information to Clause 19.1, Switch and Therapy Review Programmes which 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 was simply changed to another without any clinical assessment. 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 comprised of health professionals and/or, *inter alia*, 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, *inter alia*, prescribe.

The Panel noted Takeda's submission that when it received the complaint it did not know of any funds provided to the named health professional or the training and consultancy company for audits but during the investigation of the complaint it became aware that the named health professional had delivered two therapy reviews commissioned by clinicians who had received support for those reviews from Takeda. The Panel noted that in 2015 Takeda's Grants and Donations Committee considered a request from and made a grant to a health centre to run specialist nurse clinics at 11 local practices which would, *inter alia*, identify patients who required medication changes or optimisation or urgent interventions. Payment was made in July 2015. In July 2015 another request was considered from, and a grant paid for a similar nurse led clinic at a medical centre. Monies were paid in October 2015.

The grant request from the medical centre explained that the practice would work with a company it had previously worked with to deliver the clinics; the company was not named. The service provider and its status was not identified in any of the materials for the health centre. The Panel noted that according to Takeda in each case the practice had initially raised its need for funding with either the representative and/or his/her line manager who each advised that an application be made to the company. The Panel noted that in December 2014 the named health professional/training and consultancy company had unsuccessfully applied for a grant to fund clinics in June 2015. CRM entries (November and December 2014) showed that there had been discussions about therapy reviews including how patients would be reviewed with relevant staff including the named health professional at a different medical centre and each November meeting entry referred to the named health professional, who had attended all three meetings in his/her role as a contract nurse, undertaking the reviews. The Panel also noted

Takeda's submission that no discussion of Takeda supported therapy reviews took place at meetings with the named health professional and the GP from the health centre which had applied for a grant at the meetings in March and April 2015. In relation to the medical centre which applied for a grant, the Panel noted that at a meeting in March 2015 with the representative and regional account director, the GP at the medical centre had stated that he/she would like to do a clinical therapy review in his 3 surgeries with an independent company. The named health professional was present. When considering references to audits in the CRM entries the Panel noted that the named health professional also undertook local NHS funded clinics and that representatives were aware of these and discussed them with him. The Panel also noted that it had only been provided with CRM entries in relation to contacts with the named health professional and thus did not know what the overall level of contact and discussion had been with other health professionals at the surgeries and whether relevant discussions had occurred in the absence of the named health professional.

The Panel did not accept that Takeda first became aware of the involvement of the named health professional/the training and consultancy company with the audits when investigating the present complaint. Indeed the Panel noted that in relation to the review at the medical centre Takeda paid the monies in October 2015 directly to the training and consultancy company, rather than the surgery. The Panel noted that the representative had met the local GP at the medical centre in March 2015 along with, *inter alia*, the named health professional. The named health professional had been a consultant speaker at a Takeda internal training day two months previously. At that meeting in March the GP at the medical centre had stated he/she would like to engage an independent provider to undertake a therapy review. In the Panel's view, given the services provided by the named health professional's company, it was likely, given his presence at the meeting, that the medical centre was considering engaging the training and consultancy company. In addition Takeda's representative stated that he/she became aware whilst each therapy review was taking place that it was in fact supported by Takeda and that the named health professional was engaged to undertake it. The Panel also noted the overall level of contact between Takeda, its field staff and the named health professional during the relevant period and notes recorded on the CRM system. In addition the named health professional was a speaker at an internal Takeda training day in July 2015 and was engaged as a speaker at a Takeda promotional meeting in November 2015. In the Panel's view, at the latest, either on payment to the training and consultancy company (medical centre) or when the therapy reviews were taking place, individuals at Takeda were aware of the involvement of the training and consultancy company.

Takeda had stated that it could not comment on any correlation between the training and consultancy company activity and prescribing of a class of product but noted that use of its product was

significant within the local CCG before the grant request and that the medicine was by a significant margin the least expensive in its class available in the UK.

The Panel first had to consider Takeda's responsibility for the audits. Noting its comments above, the level of contact between the parties, previous discussions about the need for audits and advice from field-based staff to apply for funding the Panel queried the company's submission that the funding requests were unsolicited. The Panel noted the grant agreements for the therapy reviews each stated that the grant was not an inducement to, or reward for recommending or taking any decisions favourable to products or services of Takeda. The agreements also referred to the NHS body providing a brief report to Takeda on request or as agreed by the parties. The accompanying letters to the practices, however, stated only that Takeda would be extremely interested to hear about the outcomes but that the NHS body was not obliged to provide such details. In addition, Exhibit A to the agreement for the health centre stated that it was fully responsible for all aspects of the event; there was no similar statement in the agreement with the medical centre.

The Panel considered that on the available evidence neither audit was a Takeda activity. Clause 19.1 only applied to the provision of medical and educational goods and services provided by the company and thus in the Panel's view did not apply to the particular circumstances of this case. No breach of Clause 19.1 was ruled. The Panel noted that Clause 19.2 described the circumstances in which a medical and educational good and service could be provided as a donation, grant or benefit in kind. The Panel considered that Clause 19.2 applied to the provision of a restricted use grant for a therapy review to a GP practice or group of practices. The Panel considered that it was beholden on the company to undertake due diligence when making such grants. This was especially important when the restricted use grant was for an audit in an area where the company had a commercial interest. Such due diligence should ensure, *inter alia*, that the arrangements were not and could not be perceived as an inducement to prescribe.

Whilst the Panel had concerns about Takeda's governance of the restricted use grants it nonetheless noted that the complainant bore the burden of proof. The Panel did not consider that the complainant had established that provision of funds and/or the arrangements for the therapy reviews were such that they were a switch service or otherwise an inducement to prescribe as alleged. No breach of Clauses 18.1 and 19.2 was ruled.

The Panel noted the payment for an exhibition stand at a one day course held in October 2014 and run by the training and consultancy company. Other companies also exhibited. The Panel noted that an email sent in October 2014 from representative 1 to representative 2 referred to the named health professional doing extra local clinics and helping and supporting representative 1 with Takeda's product locally 'convincing GP practices to switch and use the [Takeda product] family'. The meeting

at issue was referred to as one which the named health professional had asked the representatives to support and 'in return [named health professional] has agreed that [he/she] will advocate, and help and support us in our cause in primary care with the [Takeda product] family'. Representative 2 was asked to contact the named health professional. The email in question was copied to the representatives' line manager who was the sales manager and the direct report of representative 1, a primary care representative. The Panel noted Takeda's submission that the sales manager asked representative 1 to refer the proposal to the compliance director but failed to recognise that the email suggested a link between the provision of funding and advocacy and support for Takeda's product. Takeda had not stated whether the compliance director saw the original email and, if so, what he/she did with the email or who sanctioned the payment. The representatives gave differing accounts of a subsequent meeting with the named health professional in October 2014 to discuss funding of the course at issue. Representative 1 stated that the named health professional made it clear that he/she would advocate Takeda's product in return for funding. This was denied by representative 2. A CRM report for a meeting with the named health professional in October 2014 stated that the named health professional agreed to help via speaker meetings to endorse Takeda's product across the region. The Panel also noted Takeda's submission that when payment was made for the exhibition stand space, it did not take adequate steps to ensure that it did not exceed fair market value. The Panel considered that given the link between funding and support for Takeda's product as stated in the email, the payment was contrary to Clause 18.1 and 18.6 and a breach of those clauses were ruled. The company had failed to maintain high standards and a breach of Clause 9.1 was ruled. These rulings were made under the 2014 Code.

The Panel was very concerned that despite the senior line manager being copied into the email in question no steps were taken by senior staff to review the initial arrangements or otherwise prevent payment. The level of payment was not assessed to make sure it did not exceed fair market value. In addition, the Panel noted that an inducement to prescribe was listed in the supplementary information to Clause 2 as an example of an activity likely to lead to a breach of the Code. The Panel considered that the impression created by the email brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was made under the 2014 Code.

The Panel noted its rulings of breaches of Clauses 18.1, 9.1 and 2 of the 2014 Code in relation to the arrangements and impression created by the email. The Panel considered all the circumstances surrounding the meeting of 25 October very carefully including that the representatives gave differing accounts of their meeting with the named health professional on 21 October. The Panel also noted that a ruling of a breach of Clause 2 would be the subject of an advertisement in the medical, pharmacy and nursing press. Taking all the circumstances into account, and on balance, the Panel decided not to report Takeda to the Code of

Practice Appeal Board on this point for it to consider whether further sanctions were warranted.

The Panel noted that the grants approved by Takeda were paid to the health centre in July 2015 and to the training and consultancy company with regard to the audit at the medical centre in October 2015. The clinics at the health centre would take place over 13 weeks and the services at the medical centre would be provided over 26 weeks. Both projects were sub-contracted to the training and consultancy company/the named health professional. The Panel further noted that in November 2015 and December 2015, thus certainly whilst the medical centre services were knowingly being provided by the training and consultancy company, Takeda engaged the named health professional, its director, as an expert speaker for the two promotional meetings held in a local CCG in 2015. In that regard, the Panel noted that point (vi) of the supplementary information to Clause 19.1, Medical and Educational Goods and Services, stated that sponsored health professionals should not be involved in the promotion of specific products. The Panel considered that the complainant had not established on the balance of probabilities that there was any evidence to show that his engagement to speak at the two promotional meetings was an inducement to prescribe. No breach of Clause 23.1 was ruled. Nonetheless, the Panel considered that his contemporaneous engagement in non-promotional and promotional roles either personally or via the training and consultancy company was not compatible. It did not appear that the company had undertaken any due diligence in this regard.

High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that Takeda had also been asked to respond to the requirements of Clause 21 of the 2016 Code. There was no evidence before the Panel that Takeda had engaged in any relevant activity and thus no breach of Clause 21 was ruled.

During its consideration of this case, the Panel was concerned about the 9 contacts held with the named health professional in restaurants and the company's submission that private rooms were used for promotional meetings although this was not always documented. Firstly it was entirely unclear what non promotional meetings with health professionals the company thought it could hold in the public part of a restaurant and still comply with the Code. The Panel was also concerned about the company's submission that agendas were not available for all promotional meetings so it was not possible to verify whether there was sufficient educational content to justify the provision of food. The Panel was concerned about the company's poor governance of its representatives and noted that the company was aware that its processes and controls in relation to the field force needed reinforcing and that it would initiate a detailed audit.

The Panel requested that the company be advised of its concerns.

Complaint received **3 August 2016**

Case completed **9 January 2017**