

ANONYMOUS NON CONTACTABLE v CHUGAI

Consultancy arrangements and general Code compliance

An anonymous, uncontactable ex-employee of Chugai Pharma complained about the company's appointment of a consultant and its general attitude towards Code compliance.

The complainant noted that Chugai contracted a lot of work to a pharmacist at an NHS hospital trust. The pharmacist owned a company and also worked for a number of external agencies which Chugai used on projects. A senior Chugai manager and the pharmacist were socially very close and often went on nights out. The manager often boasted of his/her relationship with the pharmacist and of how information could be obtained by 'bringing [the pharmacist] for a few drinks'. The complainant stated that he/she had heard the two favourably discussing the prescribing of Chugai medicines and had also heard the senior manager promise the pharmacist extra business by putting him/her in touch with Chugai's business partners. The complainant was uncomfortable with the closeness of the relationship but feared his/her job might be at risk if he/she highlighted it to Chugai senior management.

The detailed response from Chugai is given below.

The Panel noted that the health professional in question was engaged as a consultant by Chugai on a number of occasions between December 2011 and December 2014. Chugai had only been asked to consider activities which had taken place since March 2012. The relevant Codes were thus the 2012 and 2014 editions.

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant was non-contactable and so could not be asked to provide further details; he/she had provided no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that the engagement of the health professional had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The complainant stated that he/she had been uncomfortable with the closeness of the relationship between the health professional and the senior manager and had not felt able to bring it to the attention of other senior managers – who, it seemed from Chugai's submission, appeared to have been unaware of the closeness of the friendship.

The Panel considered that in addition to the criteria that should be met when a company used a health professional as a consultant or advisor, the impression created by the arrangements was also very important. The Panel noted Chugai's submission that the health professional was a close, personal friend of Chugai's senior manager; their friendship pre-dated the health professional's

engagement as a consultant to Chugai. In the Panel's view it was extremely important that clear distinctions were made between business and personal arrangements. Given the relationship between the health professional and the senior manager, it would be difficult for the engagement of the health professional not to be seen as a direct consequence of that relationship. The Panel noted that in many of the consultancy agreements, the senior manager had played some role, albeit that he/she did not have sole responsibility for the arrangements. Some of the senior manager's direct line reports had been responsible for selecting the health professional in question as a consultant/advisor to the company and the senior manager had then approved the budget and service fee. The Panel was concerned that despite a 'conflict of interest' register being presented to the Chugai leadership team for completion from 2013, the senior manager had not declared his/her friendship with the pharmacist. The Panel considered that the senior manager's conduct in this regard had not maintained high standards. A breach of the Code was ruled.

The Panel noted that the health professional had been paid £1,325 for services in 2012 plus £49.20 expenses; this was less than 1% of Chugai's total spend on consultants that year. In 2013 he/she had not been contracted by Chugai at all but in 2014, although he/she carried out only seven contracts for the company (less than 6% of the total number of contracts (n=123)), he was paid £28,225 plus expenses – around 29% of the company's total spend on consultants for that year (not including an additional agency project). The Panel was concerned about the impression that this might have given to those within Chugai who knew about the friendship between the health professional and the manager.

In addition to the above, in 2014 Chugai commissioned an agency to develop four projects to support the market growth of one of its medicines. The agreement between Chugai and the agency showed that the core project was to support the NHS tender for the medicine in a particular location. The total value of the project was £35,000 with some of that money (amount unknown by Chugai) being paid to the health professional via a sub-contract with the agency to build a health economic model. The Panel considered that in these circumstances it was very important that all relevant people were aware of the involvement of the health professional at issue. Further, in the Panel's view the amount paid to the health professional, if he/she was contracted personally and not via his/her company, would have to be disclosed by Chugai as part of its aggregate disclosure for 2014 given the agency had engaged him/her on behalf of Chugai.

The Panel noted its comments above and that the complainant had provided no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that his/her engagement had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The Panel thus ruled no breach of the Code. It also ruled no breach of the Code for those consultancies where the health professional had been contracted through his/her company. The Panel noted Chugai's submission that the health professional had received only limited hospitality in attending three advisory board meetings and two internal training meetings. Further, a review of expense claims by Chugai showed the company had not arranged or funded any private social occasion. The complainant provided no evidence to the contrary. No breaches of the Code were ruled.

The Panel noted its rulings above, and although it had some concerns about the consultancy arrangements it considered that Chugai had not brought discredit upon, or reduced confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

The complainant alleged that during his/her time in Chugai there was a somewhat laissez-faire attitude to ABPI compliance. A senior manager often mocked the Code and referred to it as a tick box exercise. The complainant alleged that some of the senior sales team were not ABPI certified; the company seemed to turn a blind eye to this. This attitude sometimes seemed to permeate through the company and the complainant considered that the company conveniently referred to the fact that as a Japanese company it was relationship based and that the Code was more for big pharmaceutical companies.

The Panel again noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence or cited any specific event to support his/her allegations. The Panel noted that the Code training slides provided by Chugai did not appear to be unreasonable either in tone or content. The Panel noted Chugai's submission regarding on-line training, monthly updates on the Code, the Code awareness group and the attendance of key staff at compliance conferences and considered that there was no evidence to suggest an unacceptable attitude to training or compliance. The Panel considered that on the evidence before it, there was nothing to suggest with regard to training etc, that high standards had not be maintained. No breach of the Code was ruled.

The Panel noted the allegation that senior members of the sales team, were not ABPI certified. The Panel further noted that Chugai had provided the ABPI Representatives Examination certificates for a number of its relevant senior staff and had explained why one senior manager and one director had yet to pass the examination. In that regard the Panel considered that staff had taken or would take the ABPI examination in accordance with the requirements of the Code and it ruled no breach of the Code.

The Panel noted its rulings above and ruled no breach of Clause 2.

An anonymous, uncontactable ex-employee of Chugai Pharma UK Ltd complained about the company's appointment of a consultant and general Code compliance within the organisation.

When writing to Chugai, attention was drawn with regard to consultancy arrangements, to the requirements of Clauses 2, 9.1, 18.1, 21, 22 and 23.1 of the 2015 Code and their equivalents in the 2014 and 2012 Codes. Chugai was initially asked to respond in relation to relevant activities which took place from March 2012 onwards.

On receipt of the response, which included the dates of the activities, the Panel considered that it would have to identify the relevant Codes and equivalent clause numbers. It appeared these were likely to be the 2012 and 2014 Codes and the equivalent Clauses were 2, 9.1, 18.1, 18.7 (instead of 21), 19.1 (instead of 22.1) and 20.1 (instead of 23.1).

With regard to the allegations about Code compliance, Chugai was asked to respond in relation to the requirements of Clauses 2, 9.1 and 16.1.

A Appointment of a consultant

COMPLAINT

The complainant noted that Chugai contracted a lot of work to a pharmacist at an NHS hospital trust. The pharmacist owned a company and also worked for a number of different private consultation firms which Chugai used externally on projects. The issue with the relationship was that Chugai's senior manager and the pharmacist were socially very close and often went on nights out. The senior manager often boasted of his/her relationship with the pharmacist and talked of how information could be obtained by 'bringing [the pharmacist] for a few drinks'. The complainant stated that he/she had heard the two favourably discussing the prescribing of Chugai medicines and also the senior manager promise the pharmacist extra business by putting him/her in touch with Chugai's business partners. The complainant was uncomfortable with the closeness of the relationship on occasions but feared his/her job might be in jeopardy if he/she highlighted it to Chugai senior management.

RESPONSE

Chugai stated that in common with many pharmaceutical companies, its process for contracting the provision of third party services was to use pre-approved template contracts, which were personalised for the occasion by completing facts such as the nature of the service and fee involved. Once the project received budget approval, the contract was sent to the health professional for signing. On receipt of the fully signed contract, two copies of the contract were signed by Chugai; one was returned to the service provider and the second retained and archived within Chugai.

Chugai noted that during the course of the investigation it had uncovered some administrative errors in that some of the contracts signed by the health professional had not been countersigned by Chugai. Consequently, the processes would be reviewed and staff retrained but Chugai did not consider that these errors were directly relevant to the complaint in question and they would be corrected as part of Chugai's subsequent process review.

Chugai gave a brief résumé of the pharmacist's career and noted that he/she was respected across the industry for his/her forthright views about the quality of health economic models and standards of industry-produced material and he/she worked with medical education agencies and pharmaceutical companies in this regard. Much of his/her private work was operated through his/her consultancy business established for that purpose.

Chugai stated that it had engaged the services of the pharmacist on nine occasions in the past three years. The pharmacist was engaged either personally or via his/her company as follows: as a member of three advisory boards (July 2012, September 2014 and October 2014); to deliver staff training (September 2012 and October 2014); to write a therapy area report (October 2014); to write two licensing reports (October 2012 and December 2014) and to develop material for a budget impact model and formulary pack (December 2014). Details of the time taken for each project and the fee paid was stated and a copy of each consultancy agreement was provided.

Chugai added that in April 2014, it commissioned an independent medical education agency, to develop four projects relating to one of its medicines. The agency subsequently decided, independently of Chugai to sub-contract one of these projects, the building of a health economic model, to the pharmacist. Chugai stated that it had disclosed this project for the sake of completeness as it considered that it was the only other project with which the pharmacist interacted with Chugai in a financial capacity (albeit indirectly). The total value of this project was £35,000. Chugai submitted that it did not know how much the agency had paid the pharmacist for the health economic model.

The pharmacist had been a personal friend of one of Chugai's senior managers for over ten years, which pre-dated his/her time employed by Chugai. Chugai submitted that it had played no part in arranging or funding any private social occasions and this had been verified in a review of business expense claims.

Chugai noted that the hospitality provided to the pharmacist in a business context was very limited. During the years 2012-2015, the pharmacist attended three advisory boards and spoke at two internal training meetings. Chugai submitted that the hospitality provided at these occasions was directly and proportionally related to the event during the day. Chugai had never sponsored the pharmacist to attend any national or international conference.

In summary, Chugai stated that it was confident that each of the listed engagements with the pharmacist

were appropriate, payments were of fair market value, and met the requirements of Clause 23.1 (20.1 in the 2014 Code) and all other aspects of the Code. Consequently Chugai refuted any breach of that Clause. In particular, the pharmacist was selected on each occasion for his/her knowledge of the NHS, formulary processes, health economic models and for his/her views on the general medical value of potential in-licensed treatments. There was no evidence or suggestion that his/her selection was anything other than appropriate. There was nothing to suggest his/her appointments were related to any undue influence in relation to the commercial use of individual Chugai products.

Chugai stated that it could not find any evidence of the pharmacist receiving inappropriate hospitality influence or inducement; it therefore refuted any breach of Clauses 18.1, 21 (18.7 in the 2014 Code) or 23.1 (20.1 in the 2014 Code). Further, there was no evidence of the pharmacist receiving inappropriate hospitality consequently Chugai refuted any breach of Clause 22.1 (19.1 in the 2014 Code).

In the context of the allegations that the relationship between the company (and its employees) and the pharmacist were inappropriate, Chugai categorically denied any wrongdoing. There was no evidence of any inappropriate interaction. Consequently, the company denied a breach of Clauses 9.1 or 2.

In a response to a request from the Panel, Chugai provided further information.

FURTHER INFORMATION FROM CHUGAI

Chugai submitted that as it had previously provided a full and detailed response, it was concerned at the nature and number (23) of the multi-layered follow-up questions and noted that a number of them were about the relationship between the Chugai senior manager and the pharmacist. Chugai could not see the relevance of asking the involvement of the senior manager in nominating or selecting the pharmacist as the complainant had not suggested that the selection was made by individuals who did not have the relevant expertise to make such a decision. This question appeared to relate to an implication of nepotism rather than the suitability of the individual to provide the services requested. This was beyond the scope of the Code and the company was therefore surprised to see such questions. The underlying principles and wording of the Code was focused on legitimate need for the service, relevant expertise and on the appointment of a consultant not being an inducement to prescribe or recommend etc products of the engaging company. Nevertheless Chugai answered the additional questions and provided the requested documentation. At no time was the senior manager identified by the complainant responsible for the sole authorisation of any project involving the pharmacist. Several members of staff had been involved in the various interactions with the pharmacist, including several senior managers.

What was the process for choosing the pharmacist as a potential consultant to the company?

Chugai submitted that it first engaged the pharmacist in December 2011 to sit on a joint advisory board run between Chugai and another pharmaceutical company. The pharmacist's engagement included making a presentation. Details of the fee paid was given.

Chugai noted that the Code did not require a company to specifically record why each individual service provider was selected, but that: 'the criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular consultants meet those criteria' (Clause 23.1, previously 20.1 in the 2014 Code). While the detailed reasoning was not recorded, the pharmacist would have been chosen for his/her experience as a senior pharmacist at a UK hospital trust.

Was the senior manager in any way involved in the pharmacist's selection and, if so, please give details?

Chugai's system, in common with those of other pharmaceutical companies, recorded the name of the originating project lead and the names of those who approved the budget spend. It did not record the names of all those involved in the decision-making process. Chugai named the originating project lead but stated that the senior manager who was the subject of this complaint signed the contract letter on behalf of Chugai and its business partner; he/she was present at this advisory board and presented to the group.

Please name the senior manager and personal friend of the pharmacist.

Chugai provided the name of the senior manager but it could not see how naming him/her, or any other individual, made any difference to the PMCPA consideration. The most recent version of the Chugai standard operating procedure (SOP) governing the selection and appointment of consultants was provided and it was in the process of being updated.

Relevant consultant expertise.

Chugai noted that a number of the Panel's questions related to the suitability of the pharmacist to provide the contracted services and the fact that he/she changed roles in June 2014. Chugai failed to see how a change in role rendered the previous experience of the service provider irrelevant and considered that the answers provided in its initial response were, to a large extent, self-evident.

As previously stated, the pharmacist had established a private company which provided services to industry. This in itself indicated an intention to provide services beyond those of any individual NHS position he/she held and reflected his/her overall experience as a pharmacist.

Chugai submitted that while the detailed reasoning for specifically selecting the pharmacist for each engagement was not always recorded, he/she was

chosen for his/her experience as a senior pharmacist at a UK hospital trust. Chugai was confident that the pharmacist was an appropriate choice of consultant and the relevant expertise was self-evident and explained in every situation.

Please explain the pharmacist's particular expertise. When looking for consultants to provide the services in question, were any other candidates considered? How much influence did the senior manager have in nominating and selecting the pharmacist for each role?

Chugai submitted it was self-evident that a change in role did not suddenly negate the experience obtained in previous positions; such a contention was counter-intuitive to senior management appointments in all areas of business and medicine.

Chugai reiterated its comments above regarding nepotism and the scope and principles of the Code. However, it indicated the specific involvement of the senior manager subject to this complaint in each of the five identified engagements.

September 2014: advisory board

The senior manager did not specifically select the pharmacist, but, he/she approved his/her fee (which was in accordance with other fees paid to the other advisory board members). The fee settlement was countersigned by finance.

October 2014: Therapy area report

The senior manager did not specifically select the pharmacist, but as the line manager of the organiser he/she would have overruled any inappropriate selection and additionally he/she had a role in approving the budget and service fee.

October 2014: advisory board

The senior manager did not specifically select the pharmacist, but as the line manager of the organiser he/she would have overruled any inappropriate selection and additionally had a role in approving the budget and service fee. The fee settlement was countersigned by finance.

October 2014: Staff training

The selection of the pharmacist was made by another senior manager. The senior manager in question had a role in approving the budget and service fee and the settlement was countersigned by finance.

December 2014: Budget impact model and formulary pack

Chugai noted that other potential providers were approached for this work. One was unavailable; the other submitted an unfavourable pricing proposal; the pharmacist was selected on the combined basis of his experience, price and availability. The senior manager at issue did not select the pharmacist, but as the line manager of the person who did, he/she

would have overruled any inappropriate selection and additionally had a role in approving the budget and service fee. The fee for settlement was signed by two senior directors.

Licensing reports

Regarding the remaining two engagements for the pharmacist to write a licensing report for medicines in areas of clinically unmet need; please explain the pharmacist's relevant expertise in these therapy areas. When looking for consultants to provide the services in question, were any other candidates considered? How much influence did the senior manager have in nominating and selecting the pharmacist for each role?

Chugai repeated its comments above regarding the expertise of those who selected the pharmacist, the implication of nepotism and the scope and principles of the Code. However, Chugai indicated the specific involvement of the senior manager on each of the two identified occasions.

The questions related to the suitability of the pharmacist to provide the contracted services and particularly whether he/she had the relevant therapy area knowledge. In making decisions related to the licensing-in of a product, much of the decision was related to the commercial viability based on likely uptake rather than a detailed analysis of the therapeutic condition *per se*.

The pharmacist's whole career experience was highly relevant in providing an overview of the perceived advantages and disadvantages of new therapies from the perspective of clinical uptake and therefore commercial viability.

Chugai reiterated that the pharmacist had established a private company as the vehicle by which services were provided to industry. This indicated an interest in providing services beyond those of any individual NHS position held, and reflected his/her overall experience as a pharmacist.

October 2014: licensing report

The senior manager at issue was not involved in the nomination or selection of the pharmacist for this service. The appointment was made by another senior manager, approved by the senior manager at issue, and countersigned by finance.

November 2014: licensing report

The senior manager was not involved in the nomination or selection of the pharmacist for this service. The appointment was made by another senior manager, approved by finance, and countersigned by a senior director.

During the period that the pharmacist has worked for Chugai, have any other consultants provided similar services? What proportion of Chugai's consultancy work has been awarded to the pharmacist compared with other consultants?

Chugai did not see the relevance of these questions in relation to the Code or in relation to the complaint. The Code did not limit the number of times a consultant was selected, nor did it indicate the number of times one consultant could be used compared with any other.

Self-evidently, other consultants were used at advisory boards; typically seven other individuals at each advisory board. Other health professionals had spoken at Chugai-organised internal and external meetings.

Chugai had only commissioned two reports on licensed-in medicines; both were awarded to the pharmacist with a fee of £300 paid for each.

Other consultants and agencies had been commissioned to produce materials for Chugai during the three-year period in question.

Chugai's total spend on consultants in 2014 was provided. A variety of consultancy services were managed which included advisory board attendance, speaker fees, training and support. Of the one hundred and twenty three engagements organised in 2014, seven were contracted with the pharmacist.

Chugai's total spend on consultants in 2013 was provided. A variety of consultancy services were managed which included advisory board attendance, speaker fees, training and support. Of the eighty-nine engagements organised in 2013, none were contracted with the pharmacist.

Chugai's total spend on consultants in 2012 was provided. A variety of consultancy services were managed which included advisory board attendance, speaker fees, training and support. Of the eighty-seven engagements organised in 2012, two were contracted with the pharmacist.

When the pharmacist has been asked to participate in a meeting, has the senior manager/personal friend also been present at the meeting?

Chugai failed to see the relevance of this question to the Code the principles and wording of which, quite rightly, focused on legitimate need for the service, relevant expertise and on the appointment of a consultant not being an inducement for the consultant to prescribe or recommend etc, products of the engaging company.

While Chugai did not record the attendance of individual members of staff at every meeting, the senior manager had indicated that he/she was not present in the majority of the actual meetings. However he/she was likely to have been in the Chugai office on some occasions and would have acknowledged the pharmacist during a coffee break.

Please comment specifically on the complainant's allegation that the senior manager often boasts of his/her friendship with the pharmacist and of his/her promise to put him/her in touch with, and introduce him to, Chugai's business partners to get

some extra work. Would those business partners have included a named agency?

Chugai submitted that this question related directly to the integrity and professionalism of the company and of the individual senior manager without any direct relevance to a specific clause within the Code.

Chugai submitted that it was not possible for the company to know which business partners the complainant had referred to. The senior manager categorically denied making any such statements. Chugai refuted the allegation outright.

What has Chugai done to ensure that the relationship between the pharmacist and the company/senior manager remained wholly professional and unbiased?

Chugai stated it was unclear which specific allegation in the complaint and which clause number this question related to.

Chugai stated that it had provided a copy of the consultant engagement SOP and indicated the number and nature of all the consultant engagements with the pharmacist including details of the arrangements. It submitted that all were appropriate and within the scope of the Code.

The involvement of the senior manager in question in making the selections was limited, but was irrelevant from a Code perspective unless the health professional was chosen for his/her influence on Chugai business, which was neither the allegation nor for which was there any evidence.

A 'conflict of interest' register was presented to the Chugai leadership team for completion from 2013. At that time the senior manager did not declare the friendship as a potential conflict of interest. Chugai noted that there was no requirement in the Code for a conflict of interest register.

Did Chugai know about the personal relationship between the pharmacist and its manager before it received this complaint? Has the manager ever declared a possible conflict of interest regarding his/her personal relationship?

Chugai submitted it was unclear which specific allegation in the complaint and which clause number these questions related to.

Chugai stated that some members of staff within Chugai knew about the friendship between the senior manager and the pharmacist. The investigations for this complaint revealed that it was a close friendship. It was not formally declared or registered. As a result of this complaint, Chugai would reiterate the importance of the register and also expand its use beyond the leadership team.

Regardless, Chugai had no evidence that the friendship had influenced either the selection of service provider, or that the pharmacist made inappropriate decisions about Chugai's products or business, or that any of the engagements involving

the pharmacist were in breach of the Code.

The pharmacist had not declared any conflict of interest to Chugai.

Chugai's contracts required the pharmacist to declare to his/her NHS employers any relevant interactions with Chugai. There was no requirement for Chugai to check that he/she had done so and it had not interviewed the pharmacist in the course of this investigation.

Chugai submitted it was unclear which specific allegation in the complaint and which clause number this related to.

Please provide a copy of the agreement between Chugai and its agency and any relevant correspondence between the parties relating to the pharmacist. Did Chugai provide its agency with a list of potential consultants? At what stage did Chugai know that its agent had engaged the pharmacist?

Chugai provided a copy of the agreement between Chugai and its agency.

The Chugai project was originally commissioned from a specialist agency, and the proposal provided was from the project manager. When the specialist agency was disbanded part way through the project, the project manager moved to a new agency, and transferred the project to the new company for completion. Hence the original proposal provided was signed while the project was delivered by another agency.

Chugai reiterated that its agency independently decided to secure services from the pharmacist. Chugai did not provide its agency with a list of potential consultants.

Chugai became aware of the pharmacist's involvement when the project was first proposed. The agency planned to use two consultants, the pharmacist and a second consultant. Chugai was not given the details regarding the various activities that each consultant would undertake.

In summary, Chugai stated that it stood by its original response and that it acted in good order in its selection of consultants. Chugai rejected the allegations in full.

Chugai was very concerned that the complainant was anonymous and non-contactable; he/she had not provided any evidence or material in support of the serious allegations. The company was very concerned that this allegation could damage the good reputation of the company and of the individuals concerned.

PANEL RULING

The Panel noted that the health professional in question was first engaged as a consultant by Chugai in December 2011, to sit on an advisory board, and then not again until July and September 2012 and

September, October and December 2014. Chugai had only been asked to consider activities which had taken place since March 2012. The relevant Codes were thus the 2012 and 2014 editions.

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant was non-contactable and so could not be asked to provide further details. The complainant had provided no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that his/her engagement had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The complainant stated that he/she had been uncomfortable with the closeness of the relationship between the health professional and the senior manager and had not felt able to bring it to the attention of Chugai senior management – who, it seemed from Chugai's submission, appeared to have been unaware of the closeness of the friendship.

The Panel noted that Clause 20 of the 2012 and 2014 Codes covered the use of consultants and was identical in each Code. Clause 20.1 in each Code set out the following criteria that should be met when a company used a health professional as a consultant or advisor. A written contract or agreement must be in place before services were provided and it must specify the services to be undertaken and the basis for payment. A legitimate need for such services must be identified in advance and the criteria for selecting the consultant(s) must be directly related to the identified need; the person selecting the consultant must have the expertise necessary to evaluate whether the particular consultant met those criteria. The number of consultants must be no more than reasonably necessary to achieve the identified need and the company must retain records concerning, and make appropriate use of, the services provided by consultants. The hiring of a consultant must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine and the compensation provided must reflect the fair market value of the services provided. Token consultancy arrangements were not acceptable. The contract with a consultant must include provisions that the consultant was obliged to disclose his/her consultancy whenever he/she wrote or spoke about a matter in public which was the subject of the agreement or any other issue relating to that company.

The Panel noted Chugai's concern about the number of questions it had been asked and that some of the questions were about matters which it submitted were beyond the scope of the Code. The Panel noted that the details requested were so that it could fully understand the relationship between the parties and the context in which the health professional had been engaged by Chugai to evaluate the complaint in relation to the criteria set out in Clause 20 of the 2012 and 2014 Codes.

The Panel considered that in addition to the criteria that should be met when a company used a health professional as a consultant or advisor, the impression created by the arrangements was

also very important. The Panel noted Chugai's submission that the health professional was a close, personal friend of Chugai's senior manager; their friendship pre-dated the health professional's engagement as a consultant to Chugai. In the Panel's view it was extremely important that clear distinctions were made between business and personal arrangements. Given the relationship between the health professional and the senior manager, it would be difficult for the engagement of the health professional not to be seen as a direct consequence of that relationship. The Panel noted that in many of the consultancy agreements, the senior manager had played some role, albeit that he/she did not have sole responsibility for the arrangements. Some of the senior manager's direct line reports had been responsible for selecting the health professional in question as a consultant/advisor to the company and the senior manager had then approved the budget and service fee. The Panel was concerned that despite a 'conflict of interest' register being presented to the Chugai leadership team for completion from 2013, the senior manager had not declared his/her friendship with the health professional involved. The Panel considered that the senior manager's conduct in this regard had not maintained high standards. A breach of Clause 9.1 was ruled. Although some members of staff within Chugai knew about the friendship between the senior manager and the health professional, the closeness of the friendship had only been discovered as a result of this complaint.

The Panel noted that the health professional in question had been paid £1,325 for his/her services in 2012 plus £49.20 expenses; this was less than 1% of Chugai's total spend on consultants that year. In 2013 he/she had not been contracted by Chugai at all but in 2014, although he/she carried out only seven contracts for the company (less than 6% of the total number of contracts (n=123)), he/she was paid £28,225 plus expenses – around 29% of the company's total spend on consultants for that year (not including the agency project). The Panel was concerned about the impression that this might have been given to those within Chugai who knew about the friendship between the health professional and the senior manager.

In addition to the above in 2014, Chugai commissioned an agency to develop four projects to support the market growth of one of its medicines. The agreement between Chugai and the agency showed that the core project was to support an NHS tender for its medicine in a particular location. The total value of the project was £35,000 with some of that money (amount unknown by Chugai) being paid to the health professional via a sub-contract with the agency to build a health economic model. The Panel considered that in these circumstances it was very important that all relevant people were aware of the involvement of the health professional at issue. Further, in the Panel's view the amount paid to the health professional, if he/she was contracted personally and not via his/her company, would have to be disclosed by Chugai as part of its aggregate disclosure for 2014 given the agency had engaged him/her on behalf of Chugai.

The Panel noted its comments above and that the complainant had provided no evidence to show that the health professional had not been suitably qualified to provide the services contracted or that his/her engagement had been an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The Panel thus ruled no breach of Clause 20.1 of the 2012 and 2014 Codes. It also ruled no breach of Clause 18.7 of the 2014 Code for those consultancies where the health professional had been contracted through his/her company. The Panel thus also ruled no breach of Clause 18.1 of the 2012 and 2014 Codes. The Panel noted Chugai's submission that the health professional had received only limited hospitality in attending three advisory board meetings and two internal training meetings. Further, a review of expense claims by Chugai showed the company had not arranged or funded any private social occasion. The complainant provided no evidence to the contrary. No breaches of Clause 19.1 of the 2012 and 2014 Codes were ruled.

The Panel noted its rulings above, and although it had some concerns about the consultancy arrangements it considered that Chugai had not brought discredit upon, or reduced confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

During its consideration of this matter, the Panel noted with concern that only 2 of the 9 consultancy agreements with the health professional in question had been countersigned by Chugai; one had not been signed by either party. Chugai had noted these errors and stated that procedures would be reviewed and staff retrained.

B General Code compliance

COMPLAINT

The complainant alleged that during his/her time in Chugai there was a somewhat laissez-faire attitude to ABPI compliance. A senior manager often mocked the Code and referred to it as a tick box exercise. The complainant alleged that a number of members of the senior sales team, were not ABPI certified; the company seemed to turn a blind eye to this. This laissez-faire attitude sometimes seemed to permeate through the company and the complainant stated that he/she often considered that the company conveniently referred to the fact that as a Japanese company it was relationship based and that the Code was more for big pharmaceutical companies.

Response

Chugai noted that although Clause 16.2 was not specifically listed by the case preparation manager, it would respond to the allegations concerning the ABPI Representatives Examination.

Chugai submitted that the director, referred to in the complaint, did not need to take the ABPI Representatives Examination as he/she was a national (second-line) director whose role was primarily strategic. However, Chugai decided that

he/she should sit the examination and he/she had been granted a short extension. He/she sat the examination within the extended period and was expected to pass it within the required 2 years.

The only other senior manager who had not yet passed the ABPI Representatives Examination sat the examination within the required 12-month period and was expected to pass it within the required 2 years from joining the company.

Chugai provided copies of the ABPI Representatives Examination certificates for relevant senior staff.

With regard to general Code compliance, Chugai submitted that it had developed a comprehensive range of UK SOPs to ensure that processes were in place to meet the requirements of the Code. SOPs were reviewed at least annually to ensure compliance. The 13 current SOPs covered topics including meetings and hospitality, interactions with patient organisations, use of consultants and certification. During 2015, further SOPs would be developed to address the new disclosure requirements.

All employees were required to read SOPs before undertaking any new task and at least annually, sign to confirm they had read and understood the SOPs relevant to their role according to a predefined categorisation.

Compliance staff typically attended at least two specialist compliance conferences a year to ensure maintenance of appropriate knowledge and skills.

All employees attended an induction training course (ITC) day one of which included a 45 minute presentation from compliance on the importance of compliance and the Code and of personal integrity when making business decisions. There was also a 1 hour presentation from the quality assurance department on the general SOPs; the delegates subsequently undertook self-study of the relevant SOPs and received follow-up training within their departments. New starters had to complete SOP training within one month of joining the company.

Sales teams received compliance training, at least annually, for their role. Compliance provided updates to the sales teams on developments in SOPs and the Code at internal meetings. The next update was due 23 March 2015. In addition, all sales staff undertook an annual online Code course from an independent external supplier. Compliance also ran a bi-monthly internal Code awareness group where Code-related events were discussed and company-based guidance was reviewed. Changes in guidance were then distributed to all staff.

The business subscribed to a monthly update service from an independent compliance specialist to ensure that a high awareness was maintained of evolving issues and Code cases.

All employees had a training record which was checked and signed at least annually by line managers; copies were stored in head office.

All staff had to successfully complete on-line training on changes to the Code and passed the module 'ABPI Code of Practice 2015: What is New'. All staff were required to successfully complete additional on-line training on elements that were considered high risk with regard to good governance (UK Bribery Act 2010, Data Protection Act 1998, social media awareness, and IT risks).

Chugai submitted that it operated a comprehensive governance framework, including a full suite of SOPs related to Code compliance. All employees were trained annually in SOPs relevant to their role and all received regular Code training and updates. The company denied a breach of Clauses 2, 9.1 or 16.1.

FURTHER INFORMATION FROM CHUGAI

Chugai noted that it had been asked to address the complainant's statement that a senior manager often mocked the Code and referred to it as a tick box exercise and to explain what could have led the complainant to make such an allegation. Chugai submitted that these questions related directly to the integrity and professionalism of the company and its senior manager.

Chugai stated that the senior manager was interviewed by an external compliance specialist and strongly denied making any such comments about 'tick-box exercises' and most certainly did not mock the Code. The senior manager was a champion for the Code internally and was also known to the PMCPA and the ABPI as being active in compliance and sat on compliance-related working groups and spoke at international compliance congresses. A copy of the last presentation by the senior manager at an induction training course was provided.

In summary, Chugai stated that it stood by its original response and that it acted in good order in its approach to Code compliance. Chugai rejected the allegations in full.

PANEL RULING

The Panel again noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence or cited any specific event to support his/her allegations. The Panel noted that the Code training slides provided by Chugai did not appear to be unreasonable either in tone or content. The Panel noted Chugai's submission regarding on-line training, monthly updates on the Code, the Code awareness group and the attendance of key staff at compliance conferences and considered that there was no evidence to suggest that training was a 'tick box' exercise or that the company took a laissez-faire attitude to compliance. The Panel considered that on the evidence before it, there was nothing to suggest with regard to training etc, that high standards had not be maintained. No breach of Clause 9.1 was ruled.

The Panel noted the allegation that senior members of the sales team, were not ABPI certified. The Panel further noted that Chugai had provided the ABPI Representatives Examination certificates for a number of its relevant senior staff and had explained why the director and one of the senior managers had yet to pass the examination. In that regard the Panel considered that staff had taken or would take the ABPI examination in accordance with the requirements of the Code and it ruled no breach of Clause 16.1.

The Panel noted its rulings above and ruled no breach of Clause 2.

Complaint received	26 February 2015
Case completed	12 May 2015