CASE AUTH/2741/12/14

REPRESENTATIVE v CHIESI

SOP training

A representative complained that standard operating procedure (SOP) training for a primary care sales team, which was run by a regional business manager (RBM), was such that it failed to maintain high standards and did not help Chiesi be more code compliant.

The complainant stated that the SOP training took place because Chiesi was to be audited by the PMCPA; delegates were told that the training was a 'tick box exercise to get [the PMCPA] off [Chiesi's] backs'. The RBM also said that he/she was one of the managers who would be interviewed by the PMCPA but that he/she was 'more than ready for it' and was looking forward to it. This might have just been bravado, but all of the delegates thought it was a strange way to talk about a PMCPA audit.

The complainant stated that the training was very rushed because there was a lot to get through. The delegates completed a multiple choice test and then passed their sheet to a colleague for marking and the RBM read out the answers. The complainant alleged that all of the delegates got some answers wrong but that the RBM gave instructions to rub or score out the wrong answers and then re-tick the correct box. The RBM then collected the answer sheets and stated 'but of course you all got these right, 100% otherwise we would have to do this training all again'. After the event everyone considered that the training was inadequate and a waste of time, especially as they were made to cheat to pretend that they had passed an examination that actually most of them failed.

The complainant alleged that the SOP training was inadequate and was merely a 'tick box' exercise; it showed that Chiesi was not very ethical and did not take its SOP training seriously and was more worried about passing an audit than training its staff to a sufficient level in order to be an ethical pharmaceutical company and make its representatives fully conversant with the Code.

The detailed response from Chiesi is given below.

The Panel noted that the training in question had been run by an RBM who, 8 days before the event, emailed the attendees to remind them of the importance of complying with the company SOPs, in particular those governing the support of meetings. The RBM was clear in the email that the correct application of processes was a personal responsibility as was improving compliance skills, knowledge and attitude and helping colleagues to do the same. The Panel did not consider that the email had set the training up as a tick box exercise. It was of course impossible to know what was said at the training event itself but Chiesi submitted that during its investigation the RBM denied referring to the training as a tick box exercise and none of the eight delegates interviewed had heard the training be so described. The Panel noted, however, that in the RBM's interview notes, he/she stated that he/she might have referred to the validation test as a tick box exercise as he/she needed to show that the training had been delivered and that people understood the training. Chiesi submitted that many of those interviewed had stated that they recognised the importance of the training and had left the event with a good understanding of the SOPs. The Panel was concerned that the running order provided by Chiesi failed to include the validation of the meetings SOP.

The Panel noted that the delegates were trained on six SOPs; three were updates from versions on which the delegates had been previously trained and validated (recall procedure, information requests and UK meetings) and three were new SOPs for which there had been no previous training or validation, (distribution of material, use of electronic communications and use of consultants and speakers). The Panel was concerned that delegates were only formally re-validated on their understanding of two SOPs at the meeting and their understanding of the other four SOPs, including three new ones, was only validated verbally. The formal validation of the two SOPs was by way of two multiple choice test papers, one for the meetings SOP (13 questions) and the other on the sales procedure for handling on- and off-label requests for information (7 questions). The Panel queried, given the length of the meetings SOP (12 pages) and its related guidance notes (34 pages), whether being required to answer 13 multiple choice questions in 15 minutes with a further 15 minutes for discussion was a sufficiently rigorous test of understanding. The Panel noted in that regard Chiesi's submission that the delegates had been trained and validated on the previous meetings SOP and the new version was not significantly different from the old one. Nonetheless, given the content of the day and the extent to which delegates were tested on six SOPs, three of which were new, the Panel queried the validation exercise and whether it would withstand external scrutiny. In that regard, it disagreed with Chiesi's submission that the training and validation was robust.

The Panel noted that the multiple choice papers were swapped between delegates for marking and the marked papers showed that every delegate scored 100% in both tests. The Panel was concerned, however, that three of the validation papers relating to the meetings SOP appeared to show that answers had been changed – three answers on one paper, two on another and one on the third. One of the test papers for the procedures for handling information requests showed that

one answer had been changed. The Panel noted that as only four of the validation papers overall showed that initial answers had been changed, there was insufficient evidence to support the complainant's allegation that all of the delegates got some answers wrong and that everyone was a bit confused.

The Panel noted that Chiesi had provided copies of the interview sheets from December 2014 and January 2015 for each delegate and in that regard it was concerned that each delegate was not asked a standard set of questions. For instance, in the December interviews, only three delegates were asked 'Did anyone get a question wrong?' and some were asked 'Was anyone asked to *change their answers*?' whilst others were asked 'Was anyone asked to change *an answer*?' (emphasis added). The Panel noted that a number of the interviewees stated that during the marking procedure, if any wrong answers were noted the matter was discussed in detail to ensure the correct answer was understood. Further, the RBM stated in his/her interview that where a question was answered incorrectly he/she sought to clarify the issue and then in light of discussions, in order to revalidate their understanding, the delegates were asked to identify and highlight the correct answer on the sheet. The RBM referred to the changes being evident on the hand written score sheets. The Panel considered that there was thus some evidence to support the complainant's allegation that original answers were changed but noted Chiesi's submission that this was only done after discussion so that those who had answered a question incorrectly understood the correct answer. In the Panel's view this was not necessarily unacceptable as the discussion and clarification of points could be regarded as training in itself. However, the amount of discussion needed was an important aspect and measure of the effectiveness of the initial training and in that regard the Panel considered that it would have been clearer if the results included each delegate's initial score as well as their final score. This would give a more accurate reflection of the position. The Panel appreciated that the RBM would not want anyone leaving the training without knowing all of the correct answers.

The Panel noted its concerns above and considered that based on the material before it, in so much as the validation of the six SOPs was inadequate, on the balance of probabilities, this aspect of the training had been a tick box exercise and in that regard it considered that high standards had not been maintained. A breach of the Code was ruled. The Panel noted its concerns above about the possibility of answers being changed or inserted but considered that as training had been given there was no breach of the Code.

The Panel noted its comments above and considered that the complainant had not shown that the SOP training was inadequate. No breach of the Code was ruled.

The Panel noted the complainant's serious allegations; representative training was important for the reputation of the industry as a whole. However, although noting its rulings above, the Panel considered that overall the training was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The Panel ruled no breach of Clause 2.

A representative complained about standard operating procedure (SOP) training for a primary care sales team which took place in October 2014.

COMPLAINT

The complainant stated that the training was run by a named regional business manager (RBM). Eight named individuals attended the training. An attendance sheet was signed by all present before the training commenced.

The complainant stated that the SOP training took place because Chiesi was shortly to be audited by the PMCPA; delegates were told that the training was a 'tick box exercise to get [the PMCPA] off [Chiesi's] backs'. The RBM also said that he/she was one of the managers who would be interviewed by the PMCPA but that he/she was 'more than ready for it' and actually he/she was looking forward to it. This might have just been bravado, but all of the delegates thought it was a very strange way to talk about a PMCPA audit.

The SOPs being covered at the meeting were: SOP13 meetings organised field force personnel – 38 pages; SOP252 safety event reporting – 6 pages; SOP247 electronic communication – 7 pages; SOP7 recall of materials – 9 pages; and SOP10 handling customer requests – 5 pages.

The RBM stood at the front of the room and all of the representatives sat around a table. The RBM used a projector and basically read through all of the SOPs. This was very rushed because there was a lot to get through. The RBM read through the SOPs from 10am until 1pm with a 15 minute coffee break.

There were two coffee breaks as well as lunch. At around 2pm the delegates were split into pairs and given an example of a promotional meeting that was carried out and they had to state if it fitted the meetings SOP. The delegates then discussed this as a group and it was quite unclear how this fitted into the SOP. As there was so much within the SOP, rushing once through the slides was not enough to have a full understanding. Everyone was a bit confused.

The complainant stated that delegates were then tested on the SOP training at 2:30pm. The delegates completed the multiple choice test and then had to pass their sheet to a colleague for marking and the RBM read out the answers. The complainant alleged that all of the delegates got a number of the answers wrong but that the RBM gave instructions to rub out or score out the wrong answers and then re-tick the correct box. The RBM then collected the answer sheets and stated 'but of course you all got these right, 100% otherwise we would have to do this training all again'. After the meeting everyone

considered that the training was inadequate and a waste of time, especially as they were basically made to cheat to pretend that they had all passed an examination that actually most of them failed.

The complainant alleged that the SOP training was inadequate and was merely done as a 'tick box' exercise; it showed that Chiesi was not very ethical and did not take its SOP training seriously and was more worried about passing an audit than training its staff to a sufficient level in order to be an ethical pharmaceutical company and make its representatives fully conversant with the Code. Other people that attended the meeting also considered that it was very unethical that they were made to change answers and they felt quite uncomfortable about this, but were too scared about any repercussions to say anything.

The complainant alleged that the training was such that it failed to maintain high standards, in breach of Clause 9.1, or to help Chiesi to be more Code compliant, in breach of Clause 16.1.

When writing to Chiesi, the Authority asked that in addition to the clauses cited by the complainant, it also consider the requirements of Clauses 15.1 and 2.

RESPONSE

Chiesi stated that it was disappointed to receive any complaint, more so when it was from an employee. Chiesi had a confidential 'Raising an Internal Concern' facility, available to all employees. If this had been raised through internal processes at the time, the matter would have been brought to the attention of senior managers to be fully investigated and, where required, immediate action taken.

Background

Chiesi stated that it had worked hard over recent years to enhance the compliance culture and structure within its business. One of the key changes was to ensure operational managers were focused on compliance which was afforded the same, if not greater, importance than commercial performance. The changes had been driven by Chiesi's desire for continuous improvement, as well as acting upon recommendations made following recent PMCPA audits. A key area of Chiesi's focus had been to review the overall compliance framework, develop SOPs and change the responsibility for SOP development from central medical/compliance led, to operational management led. As a result, new SOPs had been created and existing ones revised.

SOP training

Chiesi stated that on two successive days in October 2014 SOP training took place for head office employees and field based sales managers, including RBMs respectively. The training was delivered by the SOP authors.

The training for the field based managers and RBMs was designed to ensure that attendees could train the SOPs to their teams. The field based team was trained on an additional SOP (UK-SOP-0247 Use of Electronic Communication by Salesforce). The agenda had already been compiled and a late decision was taken to include UK-SOP-0247 as the final draft was then available. Following the SOP training for the field based managers, RBMs were given materials in order to train their respective teams. RBMs were instructed to deliver a similar full day event and to conduct written validations for all attendees to check understanding.

Response to complaint

Chiesi submitted that it conducted a full investigation, checked training records and reviewed the training process. Investigation meetings had been conducted with all the delegates and the RBM, with the exception of one person who had worked under contract to Chiesi at the time but no longer worked for the company; he/she had declined an invitation to be involved with an investigation meeting.

Chiesi acknowledged that it was due to be audited by the PMCPA shortly after the SOP training in question; this was a re-audit from the previous PMCPA audit conducted on 13 March 2014. Chiesi confirmed that the RBM who delivered the training was scheduled to be interviewed by the PMCPA for the audit.

Sales team training

Chiesi stated that the training at issue for eight attendees was led by the RBM; Chiesi confirmed that all those named by the complainant, including the RBM, were present at the training. The RBM had passed the APBI examination; he/she had an impeccable record and was a mentor within the RBM team. The objective for the event was to train the regional sales team on the newly created SOPs and revised SOPs applicable to their role.

In preparation the RBM met the regional compliance champion on the evening before the event to explain the format of the following day's training as they would both be present to support the event. The purpose of the meeting was to alert the compliance champion as to the questions that were likely to arise. The meeting was informal, hence no agenda was produced, and lasted for approximately 2 hours.

The training in question started at 10am and finished at 4pm. There was a scheduled coffee break at 11:15am with lunch scheduled at 12:30pm and a further coffee break at 2:30pm. The SOPs trained that day were:

UK-SOP-0007	Procedure for recall for promotional and non-promotional materials
UK-SOP-0010	Sales procedure for handling on and off-label requests for information
UK-SOP-0013	Meetings organised by field force personnel
UK-SOP-0237	Material distribution (not stated by the complainant)
UK-SOP-0247	Use of electronic communication by salesforce

UK-SOP-0253 Use of consultants and speakers (not stated by the complainant).

The complainant also incorrectly stated that 'SOP 252' on safety event reporting was trained; UK-SOP-0252 was not an allocated number for current SOPs. UK-SOP-0251 Safety Event Reporting for Chiesi Workers was referenced as part of the presentation for UK-SOP-0010 to add context but was not trained on the day.

At the start of the training session the RBM delivered a presentation to set the scene using approved training slides. This was followed by presentations on the SOPs UK-SOP-0007, UK-SOP-0010, UK-SOP-0013 (no presentation, SOP and guidance notes used), UK-SOP-0237, UK-SOP-0247 (no presentation, SOP and guidance notes used) and UK-SOP-0253. These presentations were examined only and therefore no certificates were available. Current SOPs UK-SOP-0007, UK-SOP-0010, UK-SOP-0237 and UK-SOP-0253 were provided.

The RBM provided context to the attendees by explaining how the company was performing which included reference to the March 2014 audit and the upcoming audit. The RBM explained to attendees that as part of any training the company had to provide evidence of how it had trained its representatives and that it had to confirm that individuals had received and understood the SOP training. As the RBM was scheduled to be interviewed by the PMCPA the RBM knew what documents had to be provided to demonstrate how and what had been trained. The RBM refuted the allegation that he/she had implied the training was merely a tick box exercise 'to keep the PMCPA off [Chiesi's] backs'. Chiesi confirmed that none of those interviewed heard the RBM make the alleged statement which fully corroborated the RBM's account. Many of those interviewed stated that they recognised the importance of the training.

The RBM could not remember if he/she stated that he/she was 'more than ready for the audit'. None of those interviewed could remember this being stated either. The RBM confirmed that he/she had informed the group that he/she was to be interviewed at the audit. However, this was in the context of considering that the company was in a really good place to demonstrate change and to emphasise how seriously Chiesi took compliance. Commercial activities and compliance were seen to be of equal importance to the business. None of those interviewed remarked that they considered this statement was inappropriate.

Timings

Chiesi noted the complainant's suggestion that the training was rushed with insufficient time to understand it and that everyone was a bit confused. Chiesi further noted that three SOPs already existed and therefore the training was to update the attendees on the changes. All attendees had already been trained on the previous versions. With the exception of the format of the SOPs (separated out into SOPs and guidance notes) there was no significant changes to these SOPs compared with the previous versions. UK-SOP-0237, UK-SOP-0247 and UK-SOP-0253 were new SOPs for which there was neither previous training nor validation.

The RBM delivered the presentation as briefed. This included an upfront presentation and group work to enable attendees to discuss the SOP content in detail. The SOP which was used most frequently by the field and contained the most content was UK-SOP-0013, Meetings organised by field force personnel. For this SOP the RBM had the SOP on screen and attendees had a printed copy to read. They reviewed it page by page, pausing for discussion and to clarify understanding. This was interactive with the attendees, but due to its content and more frequent use, the RBM decided to go through it as a group. For UK-SOP-0013 there was a workshop briefing presentation and three scenarios for the attendees to work through. The group re-convened to discuss and share answers.

During the investigation meetings all those interviewed were asked about the delivery and content of the training. None of those interviewed stated that the training was rushed nor left them confused. All those interviewed were asked whether they left the training with a good understanding of the SOPs and how to operate with them. All those interviewed were clear on the SOPs when they left the training. All those interviewed were asked for feedback on the training and Chiesi gave details of the comments made in this regard.

The RBM had run the same training the previous day with another group. Two attendees from that training day were also interviewed and they stated that they understood the SOPs and neither said that they were confused; their statements echoed those of the attendees, at the training in question.

Validations

Chiesi stated that the RBM gave the attendees a written validation to complete on two SOPs, UK-SOP-0010 (seven multiple choice questions (MCQs)) and UK-SOP-0013 (thirteen MCQs). The attendees were provided with validation questions and had to complete them under examination conditions. Once completed, the sheets were passed to a colleague to be marked. The RBM went through each of the questions as a group and asked the attendees in turn to answer a question. The marker then marked the sheet and passed it back to their colleague. The answers were discussed. All the interviewees confirmed that they were not asked to change the answers. However, one interviewee stated: 'I may have been cheeky as very competitive, I may have asked for my sheet back to amend an answer but [the RBM] wouldn't have been aware of this'. The answer sheets were then collected in by the RBM.

Chiesi stated that the complainant alleged that sheets were collected by the RBM with a comment 'but of course you all got these right, 100%'. The complainant also alleged that attendees were basically made to cheat to pretend that they had all passed an examination that actually most of

them had failed. The RBM confirmed that when the answer sheets were collected in, because of the training that was received on the day and the discussions that had taken place around the answers, he/she was confident that the attendees had 100% understanding. This comment was not said in the context that the complainant had stated but more as a reflection of how well the day had gone. Again, none of those interviewed stated that the comment was made in the way the complainant had implied.

Chiesi stated that it took Code compliance extremely seriously and strove to ensure that its employees were trained to the highest standard. It submitted that the RBMs were fully trained before they dedicated a full day of SOP training for their sales teams. The training sessions had a balance of upfront presentations and workshop discussions. When discussing the answers to the validations the RBM encouraged participation from the group to answer each question. Where there was any doubt or an incorrect answer the RBM clarified the point there and then. When an answer was given there was discussion and the RBM checked with the group that everyone understood the answer before moving to the next question. This was confirmed by those interviewed.

Chiesi strongly denied that the training was inadequate. Clause 15.1 stated 'Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote'. As the complaint was not about training on medicines, and as Chiesi believed that the training on SOPs was adequate as detailed above, it strongly denied a breach of Clause 15.1.

Chiesi submitted that the SOP training at issue was in addition to training on the Code which all Chiesi representatives received. As the complaint referred to SOP training and not Code training, and as Chiesi believed that the training on SOPs was adequate as detailed above, it strongly denied a breach of Clause 16.1.

Chiesi reiterated its belief that the training and validation was adequate, conducted in the spirit of the Code and had maintained high standards. Chiesi therefore denied a breach of Clauses 9.1 and 2.

In response to a request for further information, Chiesi explained that two senior managers had conducted the initial investigation. Notes from the original investigation meeting held with those who had attended the training event in question were provided. To ensure that a thorough response was provided to the Authority's request for additional information, the same investigation team conducted further enquiries with the support of an additional member of staff. The notes from the additional investigation meeting held with some of the team that attended the training at issue were provided.

Chiesi reiterated that the RBM who had delivered the SOP training had also done so in a different region the previous day which was a much larger event with delegates from the primary care and the special care divisions. As it was a larger group, the session was primarily delivered by the RBM with support from the two other facilitators. The results for this SOP validation were provided together with a summary of all the validation scores for the SOP training session run by RBMs. Chiesi noted that of the fifteen training events held, ten achieved an overall validation result of 100% for UK-SOP-0013, the lowest average score was 90%; for UK-SOP-0010, eight achieved 100% and the lowest average score was 86%. Chiesi believed the results achieved by the RBM in question were achieved by other RBMs.

As noted in the investigation meeting notes, due to the length of time between the SOP training (October 2014) and the investigation meetings (December 2014 and January 2015), those interviewed consistently commented that they could not be certain about some of their responses. One representative in December 2014 stated 'I may have asked for my sheet back to amend an answer but [the RBM] wouldn't have been aware of this'. In January 2015, the representative was re-interviewed and asked 'When we spoke to you in December you made a statement that you may have changed one of your answers but that you were not sure. If you look at the papers that have been scanned and sent to you today there does appear to be amendments. Can you tell us when during the validation process you made these changes?' The representative responded 'It may have been when I was checking my answers before I finished the paper but I can't remember. I may have changed it at this point, it looks like I changed the answer'.

In January 2015, another representative was asked 'If you look at question 7 first, it looks like you have changed your answer, can you tell us when you made these amendments to the sheet?' The representative responded 'I can't remember when I made the change. Sometimes I circle the answer, then once finished I re-read the question and answer and then amend what I have put. I know I spent a long time on one of the questions as I couldn't decide from the options; I may have changed my mind from the original answer I selected'.

A third representative in January was asked 'When we spoke to you in December you made a statement that you may have got an answer wrong but your paper looks like you got everything correct, though question 6 looks like a circle may have been rubbed out, please comment?'. The representative responded 'It looks like I changed one of my answers by rubbing one out and selecting a different answer. With regards to getting one wrong, the question I thought I got wrong isn't even a question on the paper so I think I may have just mixed up with a question I may have asked regarding what to get signed off during the actual training delivery'.

Based on all the investigation meetings and despite individuals being directly asked to comment on the changes to their papers, Chiesi was unable to ascertain when, how or who amended the papers in question. However, it was clear from the investigation meetings held in December 2014 and January 2015 that those who attended the SOP

training event at issue believed it was professional and well delivered and nobody recalled or believed anyone was asked to amend their validation sheets. Examples of quotations to support this included: 'Nobody was asked to change an answer', 'Not at all, we went through the answers as a group, there was discussion around the answers, but no one was asked to change a response' and 'No one was advised to change an answer'.

In response to a request for more information about when the changes to the validation papers might have occurred, Chiesi explained that the papers were exchanged between colleagues for marking. The correct answers were provided by individual delegates after being asked a direct question by the RBM as to what he/she believed the correct answer was. Whilst running the marking session in this way both delegates and the RBM stated that further discussions took place in order to ensure everyone was clear and fully understood. In December 2014 the RBM stated;

> 'I didn't ask people to change their answers I asked people questions such as:
>
> "what is the correct answer?", "why have you put that?", "do you understand why the answer is X?" and "what is your understanding now based on our further discussion?". I then asked delegates to revisit their answers once I was comfortable that they had confirmed their understanding to me. I wanted to ensure everyone left the room knowing the correct answer, not the wrong answer.'

As everyone got 100% the RBM was asked in January 2015 'In December you commented that if someone got a question incorrect you sought to re-validate to ensure that everyone understood. Nobody got a question wrong, everyone got 100% so what did you mean by re-validation/your response?' The RBM responded;

> 'Question 9 caused confusion therefore at the point of going through the answers delegates asked for clarity regarding venues and I sought to provide the clarity. From memory I think [two delegates] asked questions in relation to this question, I can't remember if it was before marking and whilst completing their initial response or if it was discussed during the marking stage. People asked questions during the marking stage, it might not have been because they got a question wrong, it could have been to gain clarity prior to providing an answer, [one named delegate] is the type of person who seeks clarity on the question before providing an answer.'

The RBM was also asked in January 'Do you recall when you asked people to give you their verbal answer if anyone verbally gave you an incorrect answer?' The RBM responded 'I can't recall for sure. If anyone changed an answer during the marking stage I wouldn't necessarily be aware'.

Chiesi accepted that the papers could have been amended by delegates at any point.

In response to a question about why the validation of UK-SOP-0013 did not appear on the agenda, Chiesi submitted that this was an omission by the RBM. Chiesi submitted that when planning the SOP training events, given the importance of field based employees adhering to the requirements of UK-SOP-0010 (Sales procedure for handling on and off-label requests for information) and UK-SOP-0013 (Meetings organised by field force personnel) in their role, it was felt that a documented validation was required. A significant amount of time was spent on UK-SOP-0103 as it was regularly used by field force employees in their roles, providing the clarity and guidance required on how to conduct meetings and comply with the Code. The remaining SOPs trained at the event in question were validated verbally by the RBM by asking a series of questions to test delegate understanding and so that validation was not included as an item on the agenda.

Chiesi submitted that the training was well delivered and appropriate validations were completed. Those interviewed for the investigation did not corroborate the complainant's view and the investigation confirmed that the delegates believed that the training had been well delivered and that they understood the SOPs. The investigators did not believe that the training was a tick box exercise. In addition to the interviews, Chiesi noted that piror to the event, the RBM emailed the team to highlight his/her committment to the forthcoming training event and for individuals to improve their compliance skills, knowledge and attitude. This demonstrated the importance of the event. Chiesi considered the training and validation were robust and that the complainant's allegations did not suggest that there was a need for revalidation.

Chiesi noted that the RBMs were validated in the same way during their training, the results of which were provided.

With regard to the attendees at the training event in question, Chiesi listed when and on which date they had previously been trained on UK-SOP-0007, UK-SOP-0010 and UK-SOP-0013.

Chiesi explained that one of the representatives was absent from work for several months during 2014 and subsequently received 1:1 retraining from the RBM followed up in email correspondence on 1 October 2014.

Chiesi provided a copy of UK-SOP-0204, Training Procedure for Organising Initial Training Course. Chiesi noted that at the time of the training event at issue, a number of training SOPs were in draft and nearing completion. These were now effective.

Chiesi explained that in order to ensure consistent SOP training sessions were rolled out in October, a full day 'Train the Trainer' session was delivered by its head of learning and development early in the month. At the end of the session the RBMs were validated and then instructed to replicate the event with their teams.

Chiesi reiterated that it believed that the training and validation was adequate, conducted in the spirit of the Code and had maintained high standards. Chiesi therefore denied breaches of Clauses 15.1, 16.1, 9.1 and 2.

PANEL RULING

The Panel noted that in any complaint under the Code, the complainant had the burden of proving their complaint on the balance of probabilities. The complainant in this case had made a general allegation that the SOP training had been inadequate and presented to delegates as a tick box exercise. The complainant had further alleged that during the marking of the validation papers, delegates could amend their initial answers in order to ensure that they scored 100%; the complainant stated that in reality most had failed the test.

The Panel noted that the training in question had been run by an RBM who, 8 days before the event, emailed the attendees to remind them of the importance of complying with the company SOPs, in particular the processes governing the support of meetings. The RBM was clear in the email that the correct application of processes was a personal responsibility as was improving compliance skills, knowledge and attitude and helping colleagues to do the same. The Panel did not consider that the email had set the training up as a tick box exercise. It was of course impossible to know what was said at the training event itself but Chiesi had stated that during its investigation the RBM denied referring to the training as a tick box exercise and none of the eight delegates interviewed stated that they had heard the training be so described (one delegate no longer worked for the company and had declined to be interviewed). The Panel noted, however, that in the interview notes for the RBM, he/she did state that he/she might have referred to the validation test as a tick box exercise as he/she needed to be able to evidence that the training had been delivered and that people understood the training. Chiesi submitted that many of those interviewed had stated that they recognised the importance of the training and that they had left the event with a good understanding of the SOPs and how to operate them. The Panel was concerned that the running order provided by Chiesi failed to include the validation of the meetings SOP (UK-SOP-0013).

The Panel noted that the delegates were trained on six SOPs. Three of the SOPs were updates from previous versions on which the delegates had been previously trained and validated (UK-SOP-0007 (recall procedure), UK-SOP-0010 (information requests) and UK-SOP-0013 (meetings)) and three were new SOPs for which there had been no previous training or validation (UK-SOP-0037 (distribution of material), UK-SOP-0047 (use of electronic communications) and UK-SOP-0053 (use of consultants and speakers)). The Panel was concerned that delegates were only formally re-validated on their understanding of two SOPs at the meeting (UK-SOP-0010 and UK-SOP-0013) and their understanding of the other four SOPs, including three new ones, was only validated verbally. The formal validation of the two SOPs was by way of two multiple choice test papers, one for the meetings SOP (13 questions) and the other on the sales procedure for handling on- and off-label requests for information (7 questions). The Panel queried, given the length of the meetings SOP (12 pages) and its related guidance notes (34 pages), whether being required to answer 13 multiple choice questions in 15 minutes with a further 15 minutes for discussion was a sufficiently rigorous test of the delegates' understanding. The Panel noted in that regard Chiesi's submission that the delegates had been trained and validated on the previous meetings SOP and the new version was not significantly different from the old one. Nonetheless, given the content of the day and the extent to which delegates were tested on six SOPs, three of which were new, the Panel queried the validation exercise and whether it would withstand external scrutiny. In that regard, it disagreed with Chiesi's submission that the training and validation was robust.

The Panel noted that the multiple choice papers were swapped between delegates for marking and the marked papers showed that every delegate scored 100% in both tests. The Panel was concerned, however, that three of the validation papers relating to the meetings SOP appeared to show that answers had been changed – three answers on one paper, two on another and one on the third. One delegate had originally submitted that he/she might have asked for his/her sheet back (presumably after they were swapped for marking) to amend an answer. However, when questioned again about the matter the delegate stated that he/she might have changed the answer before he/she had finished the paper; he/she could not remember. Another delegate whose paper showed that an answer had been changed had stated that he/she could not remember when he/she made the change. One of the test papers for the procedures for handling information requests showed that one answer had been changed. The Panel noted that as only three of the nine validation papers relating to the meetings SOP, and only one relating to procedures surrounding requests for information, showed that initial answers had been changed, there was insufficient evidence to support the complainant's allegation that all of the delegates got a number of answers wrong and that everyone was a bit confused.

The Panel noted that Chiesi had provided copies of the interview sheets from December 2014 and January 2015 for each delegate and in that regard it was concerned that each delegate was not asked a standard set of questions. For instance, in the first round of interviews in December 2014, only three delegates were asked 'Did anyone get a question wrong?' and some were asked 'Was anyone asked to change *their answers*?' whilst others were asked 'Was anyone asked to change *an answer*?' (emphasis added). The Panel noted that a number of the interviewees stated that during the marking procedure, if any wrong answers were noted the matter was discussed in detail to ensure the correct answer was understood. Further, the RBM stated in his/her interview that where a question was answered incorrectly he/she sought to clarify the

issue and then in light of discussions, in order to revalidate their understanding, the delegates were asked to identify and highlight the correct answer on the sheet. The RBM referred to the changes being evident on the hand written score sheets. The Panel considered that there was thus some evidence to support the complainant's allegation that original answers were changed but noted Chiesi's submission that this was only done after discussion so that those who had answered a question incorrectly understood the correct answer. In the Panel's view this was not necessarily unacceptable as the discussion and clarification of points could be regarded as training in itself. However, the amount of discussion needed was an important aspect and measure of the effectiveness of the initial training and in that regard the Panel considered that it would have been clearer if the results included each delegate's initial score as well as their final score. This would give a more accurate reflection of the position. The Panel appreciated that the RBM would not want anyone leaving the training without knowing all of the correct answers.

The Panel noted its concerns above and considered that based on the material before it, in so much as the validation of the six SOPs was inadequate, on the balance of probabilities, this aspect of the training had been a tick box exercise and in that regard the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel noted its concerns above about the possibility of answers being changed or inserted but considered that as training had been given there was no breach of Clause 16.1.

Clause 15.1 of the Code required that representatives were adequately trained. The Panel noted its comments above and considered that the complainant had not shown that the SOP training in question was inadequate. No breach of Clause 15.1 was ruled.

The Panel noted the complainant's serious allegations; representative training was important for the reputation of the industry as a whole. However, although noting its rulings above, the Panel considered that overall the training was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The Panel ruled no breach of Clause 2.

Complaint received **19 December 2014**

Case completed **12 February 2015**