

MEMBER OF THE PUBLIC v CHIESI

Payments to a health professional and certification

A complainant who described him/herself as a friend of a current Chiesi employee and stated that he/she worked in a similar, non-identical industry, complained about compliance procedures within Chiesi and also that the company provided excessive hospitality to a named professor.

The complainant understood that the Code required all standard operating procedures (SOPs) to be up-to-date and alleged that Chiesi staff ignored the SOPs that had been written, no one took ownership of them and most were out-of-date.

The complainant also alleged that Chiesi paid over and above the 'reasonable amount' allowed for hospitality under the Code. The example given was that it paid one named medical professor substantial sums of money and for him/her to fly business class whenever he/she attended conferences on the company's behalf.

The complainant further identified the company employee who had allegedly used the Zinc stamp incorrectly; the stamp should only have been used by its owner, the medical director. The stamp was incorrectly used on marketing material which was then published.

The detailed response from Chiesi is given below.

The Panel noted that according to Chiesi the named professor had travelled eighteen times at the behest of Chiesi since 1 August 2016; each time as a consultant to the company rather than a delegate. The Panel noted that the professor appeared to have travelled in premium economy for the outward journey and in business on the return journey on two separate occasions when traveling to the USA and in business class on the outward and return journey when traveling to two long haul destinations.

The Panel noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities. A judgement had to be made based on the available evidence. The Panel did not consider that the complainant had established, on the balance of probabilities, that Chiesi had provided excessive hospitality in relation to the provision of inappropriate business class flights to the named professor as alleged. No breach was ruled in that regard. The Panel did not consider that the complainant had established that Chiesi's payments and expenses to the professor were excessive or inappropriate as alleged. The company had not failed to maintain high standards and no breach was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use and no breach of Clause 2 was ruled.

The Panel did not consider that the complainant had established that the employee in question had used the medical director's stamp to approve material in order to have it signed off as alleged. Based on the narrow allegation, the Panel ruled no breaches of the Code including Clause 2.

The Panel noted that the complainant had provided no evidence in support of his/her allegation that no one at Chiesi took ownership of its standard operating procedures (SOPs), and that most were out-of-date and were ignored by staff.

The Panel was concerned to note that ten SOPs were being updated after their review date, including SOPs covering high risk activities such as the procedure for the development, approval and use of press and media activities and material and the procedure for healthcare professional's attendance at third party organised meetings in the UK and overseas. The Panel further noted that an SOP related to the subject matter of the complaint, use of consultants and speakers, was being updated. The Panel noted that all but two of the ten SOPs had effective dates of 2014. The review dates ran from 31 December 2016 to 18 November 2018. The Panel noted Chiesi's submission that those ten SOPs had been assessed as still being compliant with both the 2016 and 2019 Codes and did not pose a risk to patient safety. The Panel had not been provided with these SOPs. The Panel was concerned that the owners of the ten SOPs which had not been updated had apparently not actioned reviews prior to the review dates as required by the relevant SOP.

The Panel considered that the failure to review and, if necessary, update SOPs promptly on or before their review dates as required by an SOP gave a poor impression to staff about the importance of SOPs and compliance and might have exposed the company to compliance risk. The Panel considered that Chiesi had failed to maintain high standards in this regard and a breach was ruled.

The Panel noted the summary of adverse findings, and the corrective and preventative action taken. In the Panel's view, the complainant had not established that staff were routinely not complying with or ignoring the company's SOPs as alleged and no breach was ruled in that regard.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use and ruled accordingly.

A complainant who described his/herself as a friend of a current Chiesi employee stated that he/she worked in a similar, non-identical industry,

complained about compliance procedures within Chiesi and also that the company provided excessive hospitality to a named professor.

COMPLAINT

The complainant stated that he/she understood that the Code required all standard operating procedures (SOPs) to be up-to-date and alleged that Chiesi staff ignored the SOPs that had been written, no one took ownership of them and most were out-of-date.

The complainant also alleged that Chiesi paid over and above the 'reasonable amount' allowed for hospitality under the Code. The example given was that it paid one named professor substantial sums of money and for him/her to fly business class whenever he/she attended conferences on the company's behalf.

In response to a request for further information, the complainant alleged breaches of the following:

Clause 22.1 for paying the named medical professor more than the amount allowed under the Code. The complainant alleged that this was not a one off, rather the professor in question was Chiesi's preferred delegate so the company bent the rules with regards to him/her. The complainant advised the Authority to seek the list of payments made to the professor over the years.

Clause 4 – compliance with SOPs. The complainant alleged that Chiesi put SOPs in place just for the sake of it, they were not followed, were largely out-of-date with many deviations and no one took ownership. The complainant submitted that the Authority might wish to get a list of the deviations.

The complainant submitted that he/she was unsure which clause to cite with regard to his/her allegation that the formal advertising approval stamp (used to approve copy on Zinc) should only be used by Chiesi's medical director/other approved people within the company (in line with the SOP) but was recently used by another named employee to approve material in order to get it signed off.

Clause 2 because the above brought the industry in to disrepute.

Clause 9 because Chiesi had failed to maintain high standards.

In response to a further request for more information, the complainant submitted that the professor's payments and expenses (including business class flights) were covered by way of several contracts between him/her and Chiesi. The complainant referred to internal swirl regarding whether it would be acceptable to pay for the professor's business class flights and noted guidance in the Code allowed for the individual to pay for an upgrade and that the company might pay for this for travel over 6 hours but the Code suggested premium economy.

The complainant further identified the company employee who had allegedly used the Zinc stamp

incorrectly; the stamp should only have been used by its owner, the medical director. The stamp was incorrectly used on marketing material which was then published. The complainant alleged a breach of Clause 14.

When writing to Chiesi to advise it of the complaint, the Authority requested that it consider the requirements of Clause 2, 9.1, 14.1 and 22.1 of the Code.

RESPONSE

Chiesi submitted that it took all matters related to alleged breaches of the Code very seriously and had undertaken a thorough investigation.

In response to the alleged breach of Clause 22.1 Chiesi provided details of all flights which the professor had taken, at the behest of Chiesi, since 1 August 2016. There were four business class flights in the period in question, and on each occasion the professor acted as consultant to Chiesi and so business class travel was deemed appropriate.

Chiesi noted that the supplementary information to Clause 22.1 stated that companies should only offer or provide economy air travel to delegates sponsored to attend meetings, unless a flight was scheduled to take longer than six hours in which case companies might pay for an upgrade to premium economy or similar. As for consultants, the payment or reasonable honoraria and reimbursement of out of pocket expenses, including travel, was permissible. Given the requirements of Clause 22.1, the company did not consider that there had been a breach.

In response to the alleged breach of Clause 14.1, Chiesi submitted that the person alleged to have used the copy approval stamp was one of its managers. The person in question was not a listed signatory with the PMCPA or the Medicines and Healthcare products Regulatory Agency (MHRA) and thus was not authorised to approve material and did not certify any material as alleged.

Chiesi provided a copy of its SOP which detailed approval of material together with a copy of the approved material which it considered was that referred to by the complainant. As the material in question required examination only, there was no certificate to demonstrate certification. Details were provided. The material was examined by the then medical director (authorised signatory).

The medical director examined the items before applying his/her approval stamp on 25 May 2018. No one else had access to this stamp or indeed the medical director's login details for Chiesi's approval system.

Whilst the material was examined and approved by the medical director, he/she was not physically in the office. The employee at issue therefore applied the medical director's digital signature in the knowledge that the final content had been approved and that, consequently, the medical director was happy that the material would be sent out in his/her name.

In the circumstances set out above, Chiesi did not consider that it had breached Clause 14.1.

Further, Chiesi submitted that investigations into the allegations and in light of the facts set out above, it was confident that there had been no breach of Clause 9.1. The company prided itself on its compliance culture and established high standards of compliance and it constantly sought new and improved ways to ensure these continued. By way of example it had, *inter alia* an internal audit programme implemented a new training regime for employees, contractors and third parties and routinely followed up on initiatives to preserve and enhance the profile of compliance within Chiesi.

Chiesi submitted that it had also recently reviewed all of its SOPs and, as expected, many went above and beyond the requirements of the Code in terms of compliance obligations.

Chiesi submitted that none of its actions had brought, or would bring, the industry into disrepute and in that regard, it denied a breach of Clause 2.

In response to a request for further information Chiesi submitted that it had undertaken a thorough investigation into all payments made to the professor in question since August 2016 including honoraria and expenses. Chiesi submitted that analysis of the payments showed that Chiesi engaged the professor on a range of projects at a certain hourly rate which was both within its agreed rate card for an international Key opinion leader and was also in line with the hourly rate as described as part of a retainer consultancy service contract between Chiesi and the professor. According to Chiesi this contract was in the process of being updated; the update was initiated on 10 January 2019 which preceded correspondence from the PMCPA dated 7 February 2019 which first raised the issue of payments. Chiesi explained that during its investigation it identified an inconsistency in terms of which activities were covered and logged against the retainer consultancy service contract, and which activities were covered by separate consultancy agreements which were bespoke to specific assignments. The inconsistency was assessed by Chiesi's signatories as not being in breach of the Code or a risk to patient safety, however the update to the retainer consultancy service contract aimed to address the inconsistency.

Chiesi submitted that during its analysis of the documentation regarding all payments, it uncovered an additional flight to Europe in December 2016 which was not captured in its initial response to the PMCPA. The flight was paid for by the professor and the cost re-claimed from Chiesi. Chiesi only became aware of this omission through its in-depth analysis of invoices; it was not picked up when the professor was asked to validate the list of flights taken before Chiesi's initial response was submitted. Chiesi was unable to establish the class of travel for this additional return flight from the available invoice but as the flight was associated with a consultancy activity and not meeting attendance as a delegate it was a reasonable payment as part of reimbursement of out of pocket expenses, including

travel. Given the requirements of Clause 22.1, Chiesi did not believe there had been a breach of the Code including of Clauses 9.1 and 2.

With regard to the allegation that most of Chiesi's SOPs were out of date, Chiesi conducted a full investigation into the status of all of its SOPs. Chiesi submitted that in total it had 132 SOPs, of which 30 had been updated since September 2018 and 4 of those were beyond their review date when they were updated; none of the 4 were considered to be Code-related. Chiesi submitted that there were currently ten SOPs out-of-date; importantly those ten SOPs had been assessed by its signatories as still being compliant with both the 2016 and 2019 Codes and did not pose a risk to patient safety despite being beyond their review dates. All ten SOPs were currently under review and would be updated in due course as appropriate. Chiesi highlighted that the introduction of GDPR had created a delay in updating a number of SOPs to ensure that all activities were in line with the relevant legal requirements.

Whilst Chiesi noted that the Authority requested information only for SOPs which were relevant to the Code, it wanted to include all SOPs to demonstrate the fact that it had a comprehensive suite of SOPs covering many areas of its business and took the existence and review of and adherence to SOPs extremely seriously. Chiesi submitted that the detailed breakdown of the status of its SOPs fully supported its position that the allegation that most of its SOPs were out-of-date was incorrect. Chiesi provided SOP-0276 Production and Management of Standard Operating Procedures which was the SOP that covered its management of SOPs. In the circumstances set out above, Chiesi did not consider that there was a breach of either Clause 9.1 or 2.

With regard to the allegation that SOPs were not being followed, Chiesi submitted that it had a robust compliance culture which encompassed all aspect of its business. It had a comprehensive initial training course for all employees, and contract staff which involved training on key SOPs and there was a wider learning management system which required all new starters to read, understand and, in many cases, pass a validation in relation to SOPs. This process was repeated each time SOPs were amended or updated.

Chiesi submitted that it conducted audits on a quarterly basis to monitor and assess compliance against both its SOPs and the Code. It had, over the last 12 months, widened the scope and the frequency of audits conducted and would continue that approach throughout 2019. Chiesi provided the adverse findings and relevant outcomes from audits conducted which were germane to Code-related activities and which were undertaken in 2018 in the period leading up to and including the date of the complaint.

Chiesi noted that in some cases breaches of SOPs were identified but these were addressed by producing corrective and preventative action (CAPAs) which were then followed through to correct the behaviour in question and to seek to prevent a recurrence. Chiesi noted that it adopted a very risk

adverse approach insofar as the Code was concerned and therefore its SOPs were purposefully drafted to be more restrictive than the correlating Code provisions.

Chiesi explained that one of the audits it conducted identified a potential Code breach; one of its sales representatives was found to have sent a prescribing guidelines document to two health professionals. Chiesi conducted a thorough investigation into the matter and appropriate action was taken. After further deliberation at its Code Forum (a monthly meeting at which Directors directly concerned with the Code met to discuss any Code matters or queries, and review of the corrective actions, Chiesi concluded that it was not a matter which should be the subject of a voluntary admission.

Chiesi shared additional information to demonstrate how important compliance with the Code was to its entire business ethos. As described above, all new employees and contracted staff undertook a comprehensive initial training course on the Code and were required to pass a *bona fide* validation to confirm understanding. In order to ensure continued understanding and adherence to the Code Chiesi submitted that it also had the following initiatives in place:

- Quarterly PMCPA Code Case Reviews for head office employees, where a minimum of 4 recent Code cases were reviewed and discussed by all areas of the business. Cases were prepared (with assistance from the compliance team) and presented by employees from all areas of the business, rather than by the compliance team. Attendance and participation at these quarterly updates were mandatory for all staff whose role was related to the Code and have been in place since February 2013.
- Quarterly Compliance Champion Case Reviews, which aimed to replicate the Quarterly PMCPA Code Case Review with members of field-based teams often using cases related to field force teams. Attendance and participation at these quarterly updates were mandatory, and compliance champions were retrained on an annual basis.
- Compliance objective was included on all company employees' management by objective (MBOs). This initiative had been in place for more than 5 years.
- Monthly compliance newsletters, which were circulated to all employees to ensure that everyone had a monthly reminder as to the importance of compliance with the Code in all activities. Input into the compliance newsletter was encouraged across the business. This initiative had been in place since December 2017.
- Weekly legal and compliance 'clinics' which were intended to have protected time for any ad hoc queries related to legal and/or compliance matters. This initiative had been in place since 31 January 2019.

PANEL RULING

The Panel noted that the complainant referred to Chiesi paying over and above the reasonable amount allowed for hospitality for a named professor including paying for him/her to fly business class when attending conferences on Chiesi's behalf. The Panel noted that the complainant did not provide any evidence in support of his/her allegation with regards to excessive hospitality and provided no specific details other than referring to business class flights and payments and expenses. The Panel noted that the complainant bore the burden of proof and that complaints are judged on the evidence provided by both parties.

The Panel noted the supplementary information to Clause 22.1, meetings and hospitality, with regard to appropriate air travel for delegates. The Panel noted, however, that business class travel could be offered to those who had been engaged to chair or speak at a meeting on behalf of a company. In this regard, token consultancy arrangements must not be used to justify such travel.

The Panel noted that according to Chiesi the named professor had travelled eighteen times at the behest of Chiesi since 1 August 2016; each time as a consultant to the company rather than a delegate. The Panel noted that the professor appeared to have travelled in premium economy for the outward journey and in business on the return journey on two separate occasions when traveling to the USA and in business class on the outward and return journey when traveling to two long haul destinations. The Panel noted Chiesi's submission that it was unable to establish the class of the return flight to Italy as it was paid for by the professor and the cost reimbursed by Chiesi. All other flights were in economy.

The Panel noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities. A judgement had to be made based on the available evidence. The Panel did not consider that the complainant had established, on the balance of probabilities, that Chiesi had provided excessive hospitality in relation to the provision of inappropriate business class flights to the named professor as alleged. No breach of Clause 22.1 was ruled in that regard.

In the Panel's view, the complaint went beyond the provision of business class flights. The complainant referred to 'payments and expenses (including business class flights)' and stated that payments made to the health professional were 'more than the amount allowed under the Code'. The Panel noted that the complainant did not refer to Clause 23.1 which covered consultancy payments and neither was it raised by the case preparation manager. The Panel could therefore make no ruling with regard to Clause 23.1 but considered the matter in relation to Clause 9.1. The Panel noted its comments about the complaint and the burden of proof. The Panel did not consider that the complainant had established that Chiesi's payments and expenses to the professor were excessive or inappropriate as alleged and no

breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use and no breach of Clause 2 was ruled.

With regards to the complainant's allegation regarding the inappropriate sign-off of materials, the Panel noted Chiesi's submission that the material referred to by the complainant, did not require certification. According to Chiesi they were examined by the medical director who applied his/her approval stamp within the company's electronic approval system; no one else had access to the medical director's stamp or login details. The employee at issue then applied the medical director's digital signature to the material and sent them.

The Panel did not consider that the complainant had established that the employee in question had used the medical director's stamp to approve material in order to get it signed off as alleged. Based on the narrow allegation, the Panel ruled no breach of Clause 14.1 and subsequently no breach of Clauses 9.1 and 2.

The Panel noted that the complainant had provided no evidence in support of his/her allegation that no one at Chiesi took ownership of its standard operating procedures (SOPs), and that most were out-of-date and were ignored by staff.

The Panel noted that Chiesi had an SOP covering the production and control of standard operating procedures which stated that the business head was the ultimate owner of the document and that SOPs were to be formally reviewed within a three year period to ensure that they remained current and appropriate, or to determine whether they were still needed. The Panel noted Chiesi's submission that 30 of 132 SOPs had been updated since September 2018; of these only 4 SOPs, none of which were Code related, were beyond their review date when they were updated. The Panel was concerned to note that ten SOPs were being updated after their review date, including SOPs covering high risk activities such as the procedure for the development, approval and use of press and media activities and material

and the procedure for healthcare professional's attendance at third party organised meetings in the UK and overseas. These SOPs had effective dates in February 2014 and November 2014 and review dates in February 2017 and November 2017, respectively. The Panel further noted that an SOP related to the subject matter of the complaint, use of consultants and speakers, was being updated and had a review date in October 2017. The Panel noted that all but two of the ten SOPs had effective dates of 2014. The review dates ran from December 2016 to November 2018. The Panel noted Chiesi's submission that those ten SOPs had been assessed by its signatories as still being compliant with both the 2016 and 2019 Codes and did not pose a risk to patient safety. The Panel had not been provided with these SOPs. The Panel was concerned that the owners of the ten SOPs which had not been updated had apparently not actioned reviews prior to the review dates as required by the relevant SOP.

The Panel considered that the failure to review and, if necessary, update SOPs promptly on or before their review dates as required by SOP 0276 gave a poor impression to staff about the importance of SOPs and compliance and might have exposed the company to compliance risk. The Panel considered that Chiesi had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

The Panel noted the summary of Chiesi's audit adverse findings, and the corrective and preventative action taken. In the Panel's view, the complainant had not established that staff were routinely not complying with or ignoring the company's SOPs as alleged and no breach of Clause 9.1 was ruled in that regard.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use and ruled accordingly.

Complaint received	25 September 2018
Case completed	3 May 2019