

# ANONYMOUS, NON-CONTACTABLE EX-EMPLOYEE v CHIESI

## Alleged failure to certify materials

An anonymous, non contactable ex-employee complained that an unapproved presentation on the Code and compliance had been delivered at a Chiesi sales conference.

The detailed response from Chiesi is given below.

The Panel noted that the Code required companies to prepare and certify detailed briefing material for representatives about each medicine which they would promote. The briefing material would be used to instruct representatives about the technical aspects of a medicine and how it should be promoted.

The Panel noted that the presentation at issue was an update on various Code and compliance issues. It did not directly or indirectly refer to a medicine or how it should be promoted. In the Panel's view, the Code did not require such material to be certified. The Panel thus ruled no breach of the Code. The Panel noted that the slides that were used were closely similar to the ones intended for use. Although it was unfortunate that the intended (and examined) slides had not been used, the Panel did not consider that high standards had not been maintained; no breach of the Code was ruled including no breach of Clause 2.

An anonymous, non contactable ex-employee submitted a complaint about training delivered at the Chiesi Limited sales conference in May 2015.

### COMPLAINT

The complainant stated that a former colleague who had been at the sales conference, told him/her that, part way through a presentation, a trainer realised that the slides being projected were not those that had been approved. The trainer expressed his/her concerns directly to the audience that the slides were significantly different to those originally intended, then continued to deliver the remainder of this unapproved presentation.

The subject matter was compliance with the Code delivered by a senior manager who had reminded the audience of their ongoing obligations. The complainant's former colleague expressed empathy for the presenter but commented that the irony of the situation made it memorable and sales colleagues commented on this during the break after the presentation.

The complainant stated that he/she was more aware than his/her former colleague that using unapproved training materials was not permitted and a very

serious matter. The complainant submitted that acting on the information outlined above, after it was shared with him/her in confidence, had been a difficult decision but the complainant believed that he/she was morally obliged to inform the PMCPA.

When responding to this complaint Chiesi was asked to bear in mind the requirements of Clauses 2, 9.1, 14.1 and 15.9 of the Code.

### RESPONSE

Chiesi submitted that over the last few years it had made significant progress in its attitude and overall compliance structure. This was a continuous journey based on a solid compliance framework. Chiesi was committed to ensuring that all of its employees complied with the Code. Compliance as an objective, 'Succeeding the Right Way', was mandatory for all staff at every level.

The meeting in question was an internal Chiesi UK sales meeting held on 21 May 2015. The presenter in question was a senior manager, not a trainer, with a great deal of Code knowledge and experience who relied on the slides to simply facilitate the session.

The audience included UK sales representatives and the objective of the meeting was to update them on various company activities. The presentation in question was entitled 'Compliance Update – Succeeding the Right Way'. The objective of this 30-minute talk was to give the audience a compliance update and ensure they understood recent compliance activities in Chiesi. This was documented in the job bag summary. Chiesi submitted that the presentation therefore, *inter alia*, updated the audience on PMCPA audits at Chiesi and highlighted key dates for both transparency reporting and the 2016 Code. Chiesi submitted that the presentation was not on the technical aspects of any medicine nor did it direct the sales force on how to sell a medicine. Following guidance from a signatory and as per company procedures, the slides were examined using Zinc to ensure that the presentation was consistent in content with other presentations. Chiesi noted that the reviewer comments in Zinc were not relevant to this case as they related solely to the fact that the animated build within the powerpoint presentation could not be viewed in full by the reviewers checking the pdf.

Chiesi acknowledged that due to a miscommunication between the presenter and the staff member liaising with the speakers, the examined version of the slides was not provided to the AV production company. The slides used

were the original version sent to the AV production company in order for it to start preparing the master slide template.

Once on stage, at slide 3, the presenter realised that the slides projected were the original version. Chiesi noted that the slides used did not differ, in any meaningful way, to those that were examined, and made no difference at all to the objectives of this session and content of the presentation. With this in mind, and as author of both slide sets, in a professional and experienced manner, the presenter decided to continue. A document setting out the differences between the two versions was provided.

Chiesi submitted that as the intent and content of the slides at issue neither constituted training on a product nor instructions on how to sell a product, certification according to Clause 15.9 was not required and therefore there had been no breach in that regard. The slides were not promotional and did not require certification in accordance with Clause 14.1; thus there had been no breach of that clause. Given that there had been no breach of Clauses 14.1 or 15.9, the company had not failed to maintain high standards and, accordingly had not reduced confidence in the industry or brought it into disrepute. It therefore followed that Chiesi was not in breach of Clause 9.1 and accordingly Clause 2.

Chiesi was extremely disappointed that an ex-employee should report this to the PMCPA, given the worthy intent of the presentation.

To enhance the existing informal process and to prevent any issue arising from incorrect versions of slides being used at internal meetings, Chiesi had documented a process for managing slide presentations with written guidance and disseminated this to all those involved.

Chiesi believed that the Code neither required the presentation at issue to be certified nor examined, there was thus no case to answer. Nevertheless, Chiesi had given a clear explanation of the events that occurred and reassurance around the future use

of slides at internal meetings, irrespective of whether the Code applied.

#### **PANEL RULING**

The Panel noted that Clause 15.9 of the Code required companies to prepare detailed briefing material for representatives on the technical aspects of each medicine which they would promote. Briefing material must comply with the relevant requirements of the Code and, in particular, was subject to the certification requirements of Clause 14. Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. The supplementary information to Clause 15.9 stated that the briefing material referred to in the clause consisted of both the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel noted that the presentation at issue was an update on various Code and compliance issues. It did not directly or indirectly refer to a medicine or how it should be promoted. In the Panel's view, the Code did not require such material to be certified. The Panel thus ruled no breach of Clauses 14.1 and 15.9 of the Code. The Panel noted that the slides that were used were closely similar to the ones intended for use; they were not significantly different as stated by the complainant. Although it was unfortunate that the intended (and examined) slides had not been used, the Panel did not consider that high standards had not been maintained; no breach of Clause 9.1 was ruled. The Panel noted its rulings of no breach of the Code and further ruled no breach of Clause 2.

**Complaint received**                      **27 July 2015**

**Case completed**                              **20 August 2015**