

# ANONYMOUS v CHIESI

## Conduct of employees

The complainant, who wished to remain anonymous, alleged that a regional business manager (RBM) and an account executive, who had only been with Chiesi for five weeks, visited customers in a named location before they had been fully validated and compliant with their products. Both had previous experience in the industry but to go out and see customers before completing an initial training course should not be allowed.

The detailed response from Chiesi is given below.

The Panel noted that the Code required that 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 promoted. The Panel noted that Chiesi had provided copies of the validation score sheets from the initial training course (ITC) attended by the two new members of the field force in question. Delegates were validated on their knowledge of pharmacovigilance, the Code, NextHaler chronic obstructive pulmonary disease (COPD) summary of product characteristics (SPC), high strength Fostair and NextHaler SPC and three standard operating procedures (SOPs); there was a final validation on respiratory knowledge. The two employees passed all of the validations.

The Panel noted that the two new employees had had previous experience within the industry before joining Chiesi. Nonetheless, both had been included in the Chiesi ITC which ran for five weeks. The first two and last two weeks were spent at Chiesi head office and week three was field-based. ITC delegates had been verbally briefed not to undertake any promotion to customers during week three. The Panel noted Chiesi's detailed breakdown of the activities undertaken by the RBM and the account executive during that week; there was no evidence that either had promoted medicines to health professionals in the named location as alleged. The two new members of staff had been out on the territory on the final day of the field-based week but neither had been in the named location. There was an exchange at one practice in another location about a request for Chiesi placebo devices. The RBM acknowledged receipt of the request but stated, as per the verbal briefing which they had been given, that neither he/she nor his/her colleague could engage in conversation until they had completed their training. Another practice had discussed the types of meetings pharmaceutical companies could potentially support in the area. Chiesi submitted that there was no product promotion.

The Panel was concerned that ITC delegates were only verbally briefed about not promoting products during the field-based week given the importance of such instructions to compliance; written briefing would have been more helpful. The onus was on the complainant to prove his/her complaint on the balance of probabilities and the Panel considered

that there was no evidence to substantiate his/her allegations. The Panel considered that, on the balance of probabilities, the two employees had not promoted medicines to customers before they had passed the ITC. No breach of the Code was ruled. The Panel did not consider that high standards had not been maintained and so no breach was ruled. The Panel further ruled no breach of Clause 2.

A complainant who wished to remain anonymous, complained about two new employees of Chiesi Limited.

## COMPLAINT

The complainant alleged that a regional business manager (RBM) and an account executive, who had only been with Chiesi for five weeks, visited customers in a named location before they had been fully validated and compliant with their products.

The complainant noted that both had previous experience in the industry but to go out and see customers before completing an initial training course should not be allowed.

When writing to Chiesi, the Authority asked it to consider the requirements of Clauses 2, 9.1, and 15.1 of the Code.

## RESPONSE

Chiesi submitted that the RBM and account executive started with Chiesi in January 2016.

Both employees started the Chiesi initial training course (ITC) on 18 January 2016. The ITC was a 5-week programme and was structured as follows:

| Week | Dates               | Activity Detail  | Location    |
|------|---------------------|--|-------------|
| 1    | 18 – 22<br>January  | ITC, including Pharmacovigilance validation                                | Head Office |
| 2    | 25 – 29<br>January  | ITC, including summary of product characteristics (SPC) & ABPI validations | Head Office |
| 3    | 1 – 5<br>February   | Shadow week (territory, team and customer orientation week)                | Field Based |
| 4    | 8 – 12<br>February  | ITC, including selling skills  | Head Office |
| 5    | 15 – 19<br>February | ITC, including final examination & standard operating procedures (SOPs)    | Head Office |

Chiesi provided a copy of the formal ITC agenda.

Prior to the shadow week, the new employees were trained on product and respiratory disease knowledge, including product SPC training, pharmacovigilance and Code and formally validated via the Chiesi Learning Management Systems (LMS), an online training platform with built-in functionality to enable unique, randomised questions and tests to be completed by learners to assess and validate retention of learning knowledge. Both employees achieved the required pass marks. Chiesi provided copies of the supporting validations completed at the end of week two.

At the end of week two of the ITC, the trainer provided a full verbal brief on the purpose of the shadow week, the briefing covered the following points:

- Shadow week was an opportunity to consolidate learning by observing the conduct of others in surgery
- Provide the opportunity to develop relationships with the RBM and regional colleagues
- Instructions provided to delegates that they were not signed off to promote and were unable to engage or participate in any promotional/product discussion with any health professionals
- Delegates instructed that if they were asked a direct question about a product by a health professional, they must explain that they were in training and unable to comment
- Delegates instructed that if they were offered the opportunity to practise in call whilst shadowing an experienced account executive, they should refuse.

The RBM, the new account executive and the trainer confirmed that a detailed brief was provided and covered the purpose of the shadow week, along with the instructions not to participate in any promotional activity. The RBM and the account executive stated that they did not promote any product to a health professional during their shadow week.

After completing the shadow week, delegates returned to Chiesi head office to complete the ITC. Week four focused mainly on selling skills with the opportunity for delegates to undertake role play activity and to consolidate learning. At the start of week five, all delegates had to undertake an examination and role play validations in order to receive formal approval before undertaking any promotional activity. Chiesi provided a copy of the examination paper along with a summary of the results achieved.

During week five, the following SOPs were trained:

- UK-SOP-0247 Use of electronic communication by salesforce
- UK-SOP-0007 Procedure for the recall of promotional and non-promotional materials
- UK-SOP-0237 Materials distribution
- UK-SOP-0013 Meetings organised by field based personnel
- UK-SOP-0010 Sales procedure for handling on and off label requests for information
- UK-SOP-0225 Finance procedure for claiming business expenses.

For UK-SOP-0247, UK-SOP-0007, UK-SOP-0013 and UK-SOP-0010 delegates had to complete an electronic validation via the Chiesi LMS; they were not validated on UK-SOP-0237 and UK-SOP-0225 as these dealt solely with the internal Chiesi processes for completing expenses and ordering materials. Chiesi provided copies of the validation results and questions (where applicable), the SOPs and Guidance Notes.

Chiesi also provided copies of all the formal presentations delivered and additional material used during the ITC.

The investigation found that the slides 'CHRTD20120771 – Respiratory Disease & Asthma', were first certified in August 2012, were re-certified in July 2013 but had not been re-certified for use during the January 2016 ITC. The slides 'CHRTD20130890 – Asthma Management' were originally certified in August 2013, but had not been re-certified for use during the January 2016 ITC. Chiesi accepted that this was an error on its part and would ensure that it did not happen in the future. A medical signatory had reviewed the two sets of slides and confirmed that both were suitable for re-certification and would have been suitable for use during the January 2016 ITC.

The internal investigations found no evidence of any contact with customers in the named location as alleged. The RBM and the account executive confirmed they had not visited the named location during their ITC shadow week. Chiesi provided a breakdown of the activities covered during the shadow week for the two employees.

The 5 February was the only day on which both the new RBM and the new account executive were together during that week.

During the course of the orientation day on 5 February, the RBM showed the account executive how to navigate around the territory, calling in on surgeries to leave contact details and let them know that Chiesi had a new account executive. No product promotion occurred in any of the surgeries visited.

At one of the surgeries called upon (location named but not that named by the complainant) a nurse had asked for Chiesi placebo devices. The RBM informed the receptionist that a request had been received but would be fulfilled at a future date. During the course of this discussion, the nurse who made the request made herself known. The RBM acknowledged the nurse and repeated that the request had been received but they were unable to engage in a conversation until they had completed their training. The new account executive left his/her contact details.

On 5 February the only other direct contact the new RBM and the new account executive had with anyone other than reception staff, was with a practice manager (location named but not that named by the complainant) who provided an overview of the type of meetings the pharmaceutical industry could potentially support in the area. Chiesi submitted that there was no product promotion.

Both employees had over 20 years' experience working in the pharmaceutical industry and had passed the ABPI Examination.

Having fully investigated the complaint, Chiesi believed that a thorough training programme was provided to the new RBM and the account executive. Before starting the shadow week (week 3 of the ITC) the individuals received full training and completed validations on the Code, pharmacovigilance and product SPCs. A full verbal brief was provided by the trainer to all ITC delegates prior to the shadow week which confirmed that under no circumstances should any product promotion be conducted during the shadow week. No evidence was found during the course of the investigation that any product promotion was undertaken during the shadow week.

As demonstrated above, Chiesi strongly denied a breach of Clause 15.1 and that it had not failed to maintain high standards and accordingly had not reduced confidence in the industry or brought the industry into disrepute. It therefore followed that Chiesi denied that it was in breach of Clauses 9.1 or 2.

### **PANEL RULING**

The Panel noted there had been no changes to Clauses 2, 9.1 and 15.1 of the 2015 Code and thus it considered this case in relation to the 2016 Code.

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant had not provided any evidence to substantiate the allegations made. The case preparation manager had acknowledged receipt of the complaint and reminded the complainant that all complaints were judged on the evidence provided by the parties. The complainant was asked to provide any additional information that he/she might have to support his/her case. None was received.

The Panel noted that Clause 15.1 stated that 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 promoted. The Panel noted that Chiesi had provided copies of the validation score sheets from the ITC attended by the two new members of the field force in question. The score sheets showed that delegates were validated on their knowledge of pharmacovigilance, the Code, NextHaler COPD (SPC), high strength Fostair and NextHaler (SPC) and three SOPs; there was a final 105 question validation on respiratory knowledge. The validation results showed that the two new employees passed all of the validations.

The Panel noted that the two new employees in question had had previous experience within the

industry before joining Chiesi. Nonetheless both had been included in the Chiesi ITC which started on 18 January; the course ran for five weeks and finished on 19 February. The first two and last two weeks were spent at Chiesi head office and week three was field-based. ITC delegates had been verbally briefed not to undertake any promotion to customers during week three. The Panel noted Chiesi's detailed breakdown of the activities undertaken by the RBM and the account executive during that week; there was no evidence that either had promoted medicines to health professionals in the location named by the complainant as alleged. The two new members of staff had been out on the account executive's new territory on the final day of the field-based week but neither had been in the named location. There was an exchange at one practice in another location about a request for Chiesi placebo devices. The RBM acknowledged receipt of the request but stated, as per the verbal briefing which they had been given, that neither he/she nor his/her colleague could engage in conversation until they had completed their training. A practice director in a third location had discussed the types of meetings pharmaceutical companies could potentially support in the area. Chiesi submitted that there was no product promotion.

The Panel was concerned that ITC delegates were only verbally briefed about not promoting products during the field-based week given the importance of such instructions to compliance; written briefing would have been more helpful. Nonetheless as noted above, the onus was on the complainant and the Panel considered that there was no evidence to substantiate his/her allegations. The Panel considered that, on the balance of probabilities, the two employees had not promoted medicines to customers before they had passed the ITC. No breach of Clause 15.1 was ruled. The Panel did not consider that high standards had not been maintained and so 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.

During the consideration of this case, the Panel noted Chiesi's admission that two of the slide sets used on the ITC were last approved for use in mid 2013 – they had not been re-approved for use at the January/February 2016 ITC. The Panel noted that Chiesi had stated that it would ensure that such would not happen again. Nonetheless, the Panel requested that Chiesi be advised of its concerns in this regard particularly given the importance of certification to self regulation.

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| <b>Complaint received</b> | <b>24 February 2016</b> |
| <b>Case completed</b>     | <b>18 April 2016</b>    |