

COMPLAINANT v LEO

Conduct of Leo employees

The complainant alleged that a named Leo employee ('the Manager') had demonstrated unethical behaviour including having coerced staff into gaining competitive information.

The detailed responses from Leo are given below.

1 Allegation regarding competitor's confidential discount information

The complainant alleged that the Manager had put pressure on an employee to gain a competitor's confidential discount information. The complainant alleged that this information informed Leo's strategy for Kyntheum. The parties concerned were named by the complainant and referred to in this case report as person X (alleged coerced Leo employee) and the Manager.

The Panel noted Leo's submission that following its internal investigation, prior to the company's receipt of this complaint, it had established that some years earlier the Manager had sought information from person X, who at that time was an NHS employee. According to Leo, person X did not disclose the specific price for the comparator product but provided a price range which was used by Leo to revise the patient access scheme included in the NICE submission for Kyntheum.

The Panel noted that whilst there appeared to be some differences in the parties' accounts, Leo had confirmed that the Manager had requested from NHS staff certain information about a competitor product in relation to the discounted price offered to the NHS for the purposes of Leo preparing a submission to NICE. The Panel considered that such information about a medicine was commercially sensitive and likely to be confidential. Leo submitted that such behaviour by one of its employees was not acceptable.

The Panel considered that the complainant had not established that the Manager in question was a representative as defined by the Code and therefore the clause of the Code that related to representatives maintaining a high standard of ethical conduct was not relevant and no breach of the 2016 Code was ruled in that regard.

In the Panel's view, Leo's submission that no pressure was applied when requesting this information from the NHS employee, and that the NHS employee had only disclosed general guidance on the price of the competitor product, did not negate the impropriety of Leo's actions. It was wholly unacceptable for a pharmaceutical company employee to ask an NHS employee for commercially sensitive or confidential information about a competitor product for the purposes of its own company's commercial interests. High standards had not been obtained in that regard and a breach of the 2016 Code was ruled.

The Panel noted the length of time between Leo first being made aware of the issue and its implementation of additional training, the seniority of the Manager in question along with the important role that senior employees' had in shaping the culture of an organisation. The Panel considered that the Manager's actions, in actively seeking highly commercially sensitive and confidential information about a competitor product from NHS staff, for the purposes of Leo's own commercial interests, was a serious and extremely concerning matter such that it brought discredit upon and reduced confidence in the pharmaceutical industry and a breach of Clause 2 of the 2016 Code was ruled which was upheld on appeal by Leo.

2 2019 Clinical Pharmacy Congress Meeting

The complainant alleged that he/she was requested to misrepresent him/herself at the 2019 Clinical Pharmacy Congress Meeting. The Manager allegedly asked the complainant, who used to work in the NHS, to attend on an NHS delegate badge as this meant Leo could save money and the badge would allow the complainant into areas that pharmaceutical staff could not normally access thereby gaining valuable insights.

The complainant alleged that he/she had conversations about competitor products with several Leo competitors at exhibitor booths and discussions about Leo products with health professional delegates. The complainant stated that one exhibitor suspected fraud and asked to see the name on the NHS delegate badge.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel queried the rigour of Leo's investigation; Leo's submission was limited to the Manager's version of events. It appeared to the Panel that other Leo employees were present at the congress. Furthermore, confirmation of which pass the complainant used might have been ascertained by contacting the congress organisers for their records of attendees at sessions and the way in which attendees were registered; Leo made no submission in this regard. There was also no submission by Leo in relation to checking the company's financial records. Nonetheless, the Panel noted that the complainant bore the burden of proof.

There was no evidence before the Panel that the complainant was either instructed to use, or had used, an NHS delegate badge at the congress in question and that, in doing so, had misled exhibitors or delegates about his/her identity. Whilst noting the seriousness of the allegations, which in part related to the complainant's own alleged actions, the Panel considered, based on the lack of evidence, and the narrow allegation in relation to the delegate badge, that the complainant had not established that a breach of the Code had occurred as alleged and no breaches of the 2019 Code were ruled.

3 2019 British Association of Dermatologists (BAD) meeting

The complainant alleged that the Manager invited him/her to attend the 2019 BAD meeting but wanted to keep his/her budget down and did not purchase a pass for the

complainant. The complainant alleged that to gain entry to this meeting, the Manager instructed him/her to share passes with colleagues. The complainant further alleged that the Manager asked him/her to attend competitor stands pretending that he/she still worked for the NHS to gain competitor insights. The complainant confirmed that he/she visited seven different competitor company stands and pretended that he/she still worked for the NHS.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired.

The Panel queried the rigour of Leo's investigation; Leo's submission was limited to the Manager's version of events. It appeared to the Panel that other Leo employees were present at the meeting, and the Panel queried if Leo's investigation involved interviews with other employees. There was also no submission by Leo in relation to checking the company's financial records and other records for how many exhibitor/delegate passes it received and how many Leo employees were present at the meeting.

Nonetheless, the Panel noted that the complainant bore the burden of proof. There was no evidence before the Panel that the complainant was either instructed to use, or had used, a colleague's pass to enter the meeting and in that regard no breach of the 2019 Code was ruled.

The Panel noted the complainant's allegation that he/she had visited a number of competitor stands and pretended that he/she still worked for the NHS. The Panel considered that this was in effect a voluntary admission by the complainant of being deliberately misleading as to his/her identity and that of the company that he/she represented. Nonetheless, the complainant had provided no evidence that the alleged activity had occurred. In the Panel's view, it could not accept an admission from the complainant without any substantiating evidence. The Panel therefore ruled no breach of the 2019 Code.

The Panel further considered that the complainant had not established that the Manager had asked him/her to attend competitor stands pretending that he/she still worked for the NHS. Whilst noting the seriousness of the allegation, the Panel considered, based on the lack of evidence, that the complainant had not established that a breach of the Code had occurred and no breaches of the 2019 Code including no breach of Clause 2 was ruled in that regard.

4 Linking private payments to access to the NHS

The complainant stated that the Manager asked him/her to run an internal training session and that his/her initial idea was to involve an NHS employee. The Manager was said to be initially keen until learning that the complainant had a named health professional in mind. The Manager allegedly informed the complainant that this named health professional had been paid by Leo to run a previous training session but had subsequently refused a request from one of the field team in his/her role in the NHS. The complainant stated that the Manager made it sound like the 2 events should be linked.

The Panel noted Leo's submission that the Manager stated that he/she considered that an alternative NHS employee should be used for the training session in question, as the

one proposed by the complainant had already provided insights and the Manager wished to obtain an alternative perspective and did not want to 'over-use' this particular NHS employee.

It was not clear to the Panel what the purpose of the previous or planned training session was, nor what request the NHS employee in question had allegedly previously refused, nor what conversations were had between Leo and this NHS employee before the decision was made by Leo to use a different NHS employee for the planned training session in question.

The Panel had no evidence before it that the Manager had declined to contract with the NHS employee proposed by the complainant for the training session in question because he/she was previously paid by Leo for a service but subsequently refused a request from Leo in his/her role in the NHS. The Panel considered that the complainant had not established that a breach of the Code had occurred as alleged and no breaches of the 2019 Code were ruled including no breach of Clause 2.

The complainant alleged that a named Leo employee ('the Manager') had demonstrated unethical behaviour including having coerced staff into gaining competitive information. The complainant raised a number of matters with the PMCPA, many of which were not within the scope of the Code. There were four matters which were considered by the case preparation manager to be within the scope of the Code and these were referred to the Panel.

Background comments by Leo

Leo submitted that the complaint related to matters which occurred some years ago and that the issues raised by the complainant related to the conduct of one individual, referred to by Leo as 'the Manager'. Leo stated that no documentary evidence had been submitted by the complainant to substantiate or support his/her allegations and Leo had identified no contemporaneous documentation relating to such matters.

Leo submitted that the allegations made by the complainant in relation to the Manager were previously raised with Leo in October 2020 and were thoroughly investigated by Human Resources and Legal Departments at that time and appropriate action was taken.

Overall comments by Leo

Leo stated that its investigations into the matters raised by the complainant provided no evidence to support the allegations under Points 2-4 below or any associated breaches of the Code.

With respect to Point 1, Leo submitted that it seemed that certain information in relation to the price of a comparator product was requested by the Manager from the complainant, who was at that time working for the NHS. However, Leo stated that its investigations indicated that the information provided was of a general nature and included no specific information on the actual price or percentage discount being offered in relation to the comparator product and that the complainant provided such information voluntarily. Leo submitted that appropriate action was promptly taken in response to the matters reported under Point 1. Leo respectfully suggested that this should not be viewed as a matter of such seriousness as to warrant a finding of breach of Clause 2 of the Code.

1 Allegation regarding competitor's confidential discount information

COMPLAINT

The complainant alleged that a named Leo employee ('the Manager') put pressure on an employee to gain a competitor's confidential discount information. This employee went on and requested from a former colleague to enter the NHS database to retrieve discount information. The NHS employee agreed to provide the confidential information to the Leo employee on the condition that the Leo staff never disclose where the information came from. The Leo employee went on to share the information with the Manager. The complainant alleged that there was evidence that the Manager coerced his/her staff in gaining competitive information unethically.

In response to a question from the case preparation manager regarding the use of the information about the competitor's confidential discount, the complainant stated that there was a discussion with a health professional from a named healthcare organisation. The information was said to inform Leo's strategy for Kyntheum and targeting of health professionals in the psoriasis therapeutic area. The information was said to be used in the promotion of Leo's medicines and the parties concerned were named by the complainant and referred to in this case report as person X (coerced employee by the Manager) and the Manager.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 15.2, 9.1 and 2 of the 2019 Code in relation to this allegation.

RESPONSE

Leo summarised the allegation as the complainant stating that the Manager put pressure on a Leo employee who was at that time working for the NHS to gain competitor's confidential discount information, by asking an NHS colleague at a named healthcare organisation to access the NHS database. The information obtained was used to inform Leo's strategy for Kyntheum and to target healthcare professionals in the psoriasis therapeutic area.

Leo stated that this allegation was investigated by Leo when it was raised by the complainant in October 2020. The incident described by the complainant seemingly occurred a few years earlier, at the time of launch of Kyntheum, indicated for treatment of moderate to severe plaque psoriasis in adult patients who were candidates for systemic therapy. The Manager indicated that, at that time, Leo was developing a submission for NICE and wished to include a patient access scheme (a simple discount) in the health economic analysis, with a view to ensuring that Kyntheum would be found to be cost-effective, relative to comparator products used in the NHS.

Person X was working in the NHS at the time in question and was therefore a customer of Leo Pharma. The Manager asked person X whether the discount proposed by Leo for Kyntheum was in line with the discount offered for a comparator product and he/she indicated that the level of discount offered for the comparator was more than that proposed by Leo. Person X did not disclose the specific price for the comparator product but provided a price range. The Manager stated that no pressure was applied when requesting this information from person X and, quite clearly, he/she did not have to provide it. This information was then used by the Manager in revising the patient access scheme included in the NICE submission for Kyntheum. For the avoidance of doubt, there was no evidence that the information obtained in relation to the pricing of a comparator product was used specifically to 'target healthcare professionals' or in

any way other than for the purposes of informing the thinking and internal proposal of the patient access scheme and the NICE submission.

Leo submitted that whilst it had found no support for the assertion by the complainant that the manager pressurized or coerced person X in any way to obtain information from his/her NHS colleague or that person X was asked to or did provide specific pricing information relating to comparator products, the Manager's conduct was nevertheless not in accordance with Leo's policies and procedures and appropriate action was taken internally (details were provided).

As a result of Leo's investigation of this complaint, the following measures were taken:

- a) Further training was provided to the UK and Ireland Leadership team and to all line managers. This training involved a requirement to complete an initial 'read and understand' session, followed by a 4 hour programme which addressed issues concerning the misuse of Leo confidential information and misuse of confidential information obtained from third parties. A copy of the slides used for the training were provided.
- b) Training of new employees includes use of information from former workplaces.

In summary, following investigation, Leo confirmed that the Manager had sought information from an NHS employee regarding the discounted price offered to the NHS for a comparator product to Kyntheum, for the purposes of preparing a submission to NICE. The information requested and obtained had involved general guidance on price (whether the discount for the comparator product was more than that proposed for Kyntheum and information of the price of the comparator price within a range) rather than specific information on the percentage discount. The NHS employee concerned provided such information voluntarily. Despite this, Leo concluded that such activity was not consistent with its Code of Conduct and appropriate action was taken including a requirement for further relevant training. Leo's responses to the specific clauses of the Code identified were as follows:

- Clause 15.2

Clause 15.2 covers the conduct of 'representatives' and states that they 'must at all times maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code'.

The Manager, whose conduct is the subject of this complaint, was not a representative. While therefore, Leo accepted that all its staff should maintain a high standard of ethical conduct, Clause 15.2 (which is limited to the conduct of representatives) was not applicable.

- Clauses 9.1 and 2

The seeking of business intelligence is common practice within the pharmaceutical industry. However, Leo submitted that it set high ethical standards for its staff, as reflected in the terms of the LEO Pharma Code of Conduct (on which staff were trained) as well as other policies and procedures. While therefore, the NHS employee who provided information regarding a comparator product did so voluntarily and disclosed only general guidance on

the price of the comparator product, Leo did not believe the request to the NHS for such information was acceptable. Once the matter was drawn to its attention in 2020, Leo conducted an investigation and promptly took appropriate action including the institution of additional training to reinforce Leo's ethical standards among its staff.

In these circumstances, while the Panel might conclude that the activities of the Manager amounted to a breach of Clause 9.1, Leo respectfully suggested that they did not fall within the category of the most serious cases that should result in a finding of breach of Clause 2 of the Code.

Leo submitted, for completeness, that the matter addressed above was the only example of alleged 'unprofessional or unethical behaviour' specifically identified in the document provided by the complainant.

PANEL RULING

The Panel noted the complainant's allegation that the Manager put pressure on a Leo employee (person X), who formerly worked for the NHS, to gain a competitor's confidential discount information; person X requested a former colleague to enter the NHS database to retrieve the discount information which was then shared with the manager. The complainant further alleged that information about the competitor's discount was used in a discussion with a health professional from a named healthcare organisation and the information was said to inform Leo's strategy for Kyntheum, targeting of health professionals in the psoriasis therapeutic area and in the promotion of Leo's medicines.

The Panel noted that Leo's submission in relation to this alleged activity differed to the account described by the complainant. Leo submitted that following its internal investigation in 2020, prior to the company's receipt of this complaint in July 2021, it had established that, some years earlier, the manager had sought information from person X, who at that time was an NHS employee and a customer of Leo's; the information sought was regarding the discounted price offered to the NHS for a comparator product to Kyntheum for the purposes of preparing a submission to NICE. According to Leo, the Manager asked person X whether the discount proposed by Leo for Kyntheum was in line with the discount offered for a comparator product and person X indicated that the level of discount offered for the comparator was more than that proposed by Leo. According to Leo, person X did not disclose the specific price for the comparator product but provided a price range. This information was then used by the Manager in revising the patient access scheme included in the NICE submission for Kyntheum. Leo submitted that person X had provided the information voluntarily and that no pressure was applied when requesting this information.

The Panel noted that Leo had been asked to respond in relation to the 2019 Code. The Panel noted that the 2016 Code was the relevant Code at the time of the alleged activity and therefore it would make its rulings under the 2016 Code. Clauses 2, 9.1 and 15.2 were similar in the 2016 and 2019 Codes.

The Panel noted that Leo's response at Point 1, and in its overall comments, suggested that the complainant was person X. However, the Panel did not know the identity of the complainant as he/she had not disclosed his/her name to the PMCPA.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel was not an investigatory body as such; it made its rulings on the evidence provided by both parties and the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel noted that whilst there appeared to be some differences in the parties' accounts, Leo had confirmed that the manager had requested from NHS staff certain information about a competitor product in relation to the discounted price offered to the NHS for the purposes of Leo preparing a submission to NICE. The Panel considered that such information about a medicine was commercially sensitive and likely to be confidential. Leo submitted that such behaviour by one of its employees was not acceptable.

Clause 15.2 of the 2016 Code stated that representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code. Clause 1.7 defined a representative as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.

The Panel noted Leo's submission that the Manager was not a representative. The Panel noted that the definition of a representative was wide and could cover the activities of those employees that companies might not call representatives. The Panel did not have the role description of the Manager in question and thus did not know what activities he/she performed; Leo made no submission in that regard. In relation to this matter, on the evidence before it, the Panel considered that the complainant had not established that the Manager in question was a representative as defined by the Code and therefore Clause 15.2 was not relevant. No breach of Clause 15.2 of the 2016 Code was ruled in that regard.

In the Panel's view, Leo's submission that no pressure was applied when requesting this information from the NHS employee, and that the NHS employee had only disclosed general guidance on the price of the competitor product, did not negate the impropriety of Leo's actions. In the Panel's view, it was wholly unacceptable for a pharmaceutical company employee to ask an NHS employee for commercially sensitive or confidential information about a competitor product for the purposes of its own company's commercial interests. High standards had not been obtained in that regard and a breach of Clause 9.1 of the 2016 Code was ruled.

The Panel queried Leo's submission that once the matter was drawn to its attention in October 2020, it conducted an investigation and promptly took appropriate action including the institution of additional training to reinforce Leo's ethical standards among its staff. The copies of the slides used for this training provided by Leo were dated 15 October 2021; ie a year after the matter was first drawn to its attention in October 2020 and after Leo was informed that a complaint had been made to the PMCPA in July 2021.

Clause 2 is a sign of particular censure and reserved for such use. The supplementary information to Clause 2 listed activities likely to be in breach of this clause which included conduct of company employees that fell short of competent care. The Panel noted the length of time between Leo first being made aware of the issue and its implementation of additional training, the seniority of the Manager in question along with the important role that senior employees' had in shaping the culture of an organisation. The Panel considered that the manager's actions, in actively seeking highly commercially sensitive and confidential information about a competitor product from NHS staff, for the purposes of Leo's own commercial interests,

was a serious and extremely concerning matter such that it brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 of the 2016 Code was ruled. This ruling was appealed by Leo.

APPEAL BY LEO

Leo submitted that this allegation, together with other matters, was first raised by the complainant directly with Leo Pharma Global Compliance in October 2020. The matter was taken very seriously and Global Compliance promptly commenced an investigation, including review of documents and interviews with relevant company employees. The issues were complex and a substantial period of time was required to complete the necessary inquiries. Following the investigation by Global Compliance, their findings were forwarded to Human Resources for appropriate action. Prior to the COVID-19 pandemic, interviews conducted in the context of compliance investigations had proceeded on a face-to-face basis. However, following the various periods of 'lockdown' mandated during the pandemic, there was a switch to virtual interviews. The changes in arrangements and procedures, together with the disruption caused as a result of the pandemic and different periods of lockdown in UK and Denmark inevitably meant that the investigations took longer than they would otherwise have done.

Following investigation, Leo was satisfied that this was an isolated incident, with no evidence that similar requests had been made on other occasions; appropriate action was taken promptly, in accordance with Leo's internal procedures, including that further mandatory training was implemented to reinforce Leo's ethical standards with all employees.

Leo submitted that the actions of the Manager, contrary to the company's policies and procedures – as emphasized in training provided to the Manager prior to the incident at issue – did not fall within the category of the most serious cases, warranting a finding of breach of Clause 2 of the Code, particularly given the company's prompt investigation and response to the complainant's original notification of the issue in October 2020, prior to the involvement of PMCPA.

Leo noted that the Panel ruled breaches of Clauses 9.1 and 2 of the 2019 Code. The reasons given for the Panel's finding of breach of Clause 2 were:

- i) The length of time between Leo being made aware of the issue and its implementation of additional training;
- ii) The seniority of the Manager, together with the important role that senior employees had in shaping the culture of an organisation; and
- iii) The nature of the Manager's actions in actively seeking highly commercially sensitive and confidential information about a competitor product from NHS staff for the purposes of Leo's own commercial interests.

Leo submitted that activities such as that at issue in this complaint, which related solely to the actions of one employee, were properly considered through internal processes, rather than through the PMCPA complaints procedure. In this case, the issue was thoroughly and comprehensively investigated by Leo and appropriately addressed prior to receipt of the complaint from PMCPA. Leo submitted that it therefore believed there were good grounds for concluding that the complaint should not result in findings of a breach of either Clause 9.1 or Clause 2 of the 2016 Code and for that reason asked the Appeal Board to set aside both rulings. [Note Leo had provided its undertaking and assurance in respect of the Panel's ruling

of a breach of Clause 9.1 and Leo subsequently confirmed in writing that it was only appealing Clause 2]. This appeal, however, focussed on the Panel's ruling of breach of Clause 2 and was based on four grounds, which addressed the Panel's reasons under (i) - (iii) above:

- The Panel's misunderstanding of the timing of Leo's response to the notification of the substance of the complaint in October 2020 (reason (i) listed above).
- The fact that the actions of the Manager were contrary to Leo policies and procedures, as reinforced in training provided to the Manager and other Leo employees prior to the incident in question.
- That, irrespective of the actions of the Manager, Leo's culture was not one where confidential information was requested from third parties.
- The fact that, while Leo did not defend or support the activity at issue, the company suggested it did not fall within the scope of Clause 2 of the 2016 Code.

Leo submitted that the Panel misunderstood the scope and timing of Leo's response to the notification of the substance of the complaint in October 2020. The Panel's ruling that there had been a breach of Clause 2 of the Code was based, in part, on its belief that Leo had not acted promptly to investigate and take action in relation to the substance of this complaint, once the issue was drawn to its attention.

In fact, following preliminary investigation of the issues raised by the complainant, an initial email was sent to all Leo UK employees in February 2021, requiring completion within one month of training on principles of competition law and use of social media. Additional mandatory training on competition law was provided in April 2021, to the team involved with the launch of another medicine. In May 2021, all UK/Ireland managers and the leadership team were notified of further compulsory training on Competition Law and the Leo Code of Conduct and Marketing Ethics, which then took place on 2 July 2021. (This training used the slides attached to Leo's response to the complaint dated 15 October 2021, which the Panel concluded incorrectly, had been delivered on that date). Details of training and associated actions which followed communication of the internal complaint in October 2020 were provided.

In summary, Leo submitted that it had acted promptly to investigate the matters raised in the complaint notified in October 2020 and, even before those investigations had been completed, instituted measures to reinforce the content of the Leo's Code of Conduct and Leo's policies and procedures directed towards the maintenance of ethical commercial practices. Such investigation and subsequent measures to address the resulting findings had been completed before Leo was notified of the complaint by the PMCPA on 29 July 2021. This part at least of the Panel's reasoning justifying a finding of breach of Clause 2 of the Code therefore fell away.

Leo submitted that the Manager's actions were contrary to Leo's policies and procedures as reinforced in training provided prior to the incident in question.

Leo submitted that its understanding was that the request to the NHS employee was for general guidance regarding the level of discount proposed for Kyntheum relative to other products and not for specific pricing information and the NHS employee provided such guidance willingly and voluntarily, such actions were nevertheless contrary to Leo's policies and procedures

All Leo employees underwent regular training, including training which reinforces the standards set out in the company's relevant policies and procedures. The Managers training records were up to date with all the relevant training. Leo had taken steps, prior to the incident at issue, to ensure that all Leo employees were fully trained in their obligations to adhere to Leo's Code of Conduct.

Leo submitted that its culture was not one where confidential information was requested from third parties. In finding that the actions of the Manager resulted in a breach of Clause 2 of the Code, the Panel referred to the seniority of the Manager and the important role that senior employees have in shaping the culture of an organisation.

Leo submitted that whilst the long period of time which had elapsed since the incident in question, including the change in some senior members of staff, –which had inevitably affected the company's ability to investigate these matters, a formal risk assessment in order to understand whether the incident in question was an isolated occurrence was carried out in February 2021. The result of that assessment confirmed that this was an isolated incident and that the company had consistently trained its employees that they should adhere to high ethical standards.

Leo submitted that it had further strengthened its compliance culture since early 2021 (details provided).

Leo submitted that the fact that, whilst Leo did not defend or support the activity in issue, it did not fall within the scope of Clause 2 of the 2016 Code.

Clause 2 of the 2016 Code stated:

'Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.'

Clause 2 was therefore strictly limited to activities and materials which were promotional. However, the activity at issue in this case was not one that fell within the list of promotional activities in Clause 1.2 of the Code and, while the definition of promotion under the Code was broad, Leo respectfully suggested that it did not include matters, such as the request made by the Manager, which related to a competitor product rather than promoting any Leo product. Leo noted, for completeness that submissions to HTA bodies, such as NICE were expressly listed as falling outside the definition of promotion:

'Information supplied by pharmaceutical companies to national public organisations, such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is exempt from the Code provided the information is factual, accurate and not misleading.'

Leo was strongly opposed to the activity at issue, as demonstrated by the content of its internal procedures, employment contracts and training. Nevertheless, Leo submitted that such matters did not fall within the scope of Clause 2 of the 2016 Code and were more appropriately addressed through internal disciplinary procedures and training, as had been conducted in relation to this matter.

Overall, Leo agreed that the Manager's actions were contrary to Leo's policies and procedures. Leo respectfully suggested that in general such matters should be addressed through internal

processes (as they were on this occasion) rather than through the Code. The specific activities in this case did not fall within the scope of Clause 2 of the 2016 Code and, in any event, in view of the efforts made by the company, both before the incident in question and after the issue was notified to it by PMCPA, a finding of breach of Clause 2 was not appropriate.

COMMENTS FROM THE COMPLAINANT

The complainant did not provide a response to Leo's appeal.

APPEAL BOARD RULING

The Appeal Board understood from Leo that following its internal investigation in October 2020 it had established that the Manager in question had sought information from person X in relation to the discounted price offered to the NHS for a comparator product to Kyntheum. That was before the company's receipt of this complaint in July 2021. Leo accepted that the Manager had sought the information for the purposes of preparing a submission to NICE. Person X was at that time an NHS employee. Leo stated that its investigation did not ascertain exactly what information was requested; Leo said that the Manager had not requested the specific price discount but rather a range, but that Leo did not know what the range was.

The Appeal Board considered that Leo's inability to give further details was an indication that either Leo's investigation into the matter was not sufficiently thorough or that Leo's investigation had obtained such information but was unwilling to share it with the Appeal Board.

Nonetheless, the Appeal Board considered that even if the Manager had only requested the competitor's discount price range, and not the specific discount, such information was still confidential and would be of commercial interest to Leo.

The Appeal Board did not accept Leo's submission that Clause 2 of the 2016 Code was strictly limited to activities and materials which were promotional and that it was not applicable to the matter at issue as submissions to NICE were expressly listed as falling outside the definition of promotion.

The Appeal Board noted that Clause 2 applied to activities associated with promotion, which was much wider than promotional activity. The Appeal Board considered that obtaining confidential information from an NHS employee about a competitor's discounted price was clearly performed for the company's own commercial advantage with regard to the use of Kyntheum and given the broad definition of promotion at Clause 1.2 the Appeal Board considered that the conduct of the manager in question was associated with promotion.

The Appeal Board noted that Leo had provided more information than it had provided to the Panel about the actions it had taken since the complaint was raised internally in October 2020. The Leo representatives at the appeal stated that the date field on the presentation automatically updated to the date it was opened and thus, in error, updated to 15 October 2021, the date of its response to the Panel. However, Leo said that this training had taken place on 2 July 2021, prior to Leo's receipt of this complaint on 29 July 2021. The Appeal Board considered, from the additional information that Leo had provided for its appeal, that it appeared that Leo had made efforts to address the issue after the matter was raised internally in October 2020 and that it had implemented preventative measures such as additional training for employees prior to October 2021.

Nonetheless, a majority of the Appeal Board considered that Leo did not fully appreciate the seriousness of the issue in relation to the Code. Whilst the Appeal Board accepted that the improper conduct by the Manager appeared to be an isolated occurrence and there was no evidence that the seeking of confidential competitor discount information from NHS staff had occurred elsewhere or was encouraged by Leo, the Appeal Board noted the seniority of the Manager. The Appeal Board considered that such a senior employee had an important role in shaping the culture of an organisation. The Appeal Board concluded that his/her actions, in actively seeking confidential discount price information about a competitor product from NHS staff, for the purposes of Leo's own commercial interests, was a serious matter which brought discredit upon, and reduced confidence in, the pharmaceutical industry, and the Appeal Board upheld the Panel's ruling of a breach of Clause 2 of the 2016 Code. The appeal was unsuccessful.

2 2019 Clinical Pharmacy Congress Meeting

COMPLAINT

The complainant alleged that he/she was requested to misrepresent him/herself at the 2019 Clinical Pharmacy Congress Meeting. The manager asked the complainant to attend the Clinical Pharmacy Congress meeting on behalf of Leo. . The Manager asked the complainant, who had previously worked for the NHS, to attend on an NHS delegate badge as this meant Leo could save money and the badge would allow the complainant into areas that pharmaceutical staff could not normally access thereby gaining valuable insights. The complainant stated that this felt very uncomfortable, but as he/she was keen to get on with the Manager he/she did as asked but was concerned that this was a breach of Clause 15.5.

In response to a request for further information in relation to why the complainant alleged a breach of Clause 15.5, and if the complainant spoke to NHS staff and others, the complainant responded, yes; the conversations were about competitor products with several Leo competitors at exhibitor booths and discussions about Leo products with healthcare professional delegates. The complainant stated that one exhibitor suspected fraud and asked to see the name on the NHS delegate badge.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 15.5, 9.1 and 2 of the 2019 Code in relation to this allegation.

RESPONSE

Leo stated that the complainant alleged that the Manager asked him/her to attend the 2019 Clinical Pharmacy Congress meeting on behalf of Leo but using an NHS delegate badge as this would allow Leo to save money. The NHS delegate badge would also permit entry to areas that Leo, as a pharmaceutical company, could not normally access, thereby gaining 'valuable insights' as a result of discussions with Leo's competitors at exhibitor booths and discussions about Leo products with health professional delegates.

Leo stated that this allegation was investigated when it was raised by the complainant in October 2020 and no substantiating evidence was found. The manager stated that most members of his/her team attended the Clinical Pharmacy Congress Meeting, which was sponsored by Leo. As a result of such sponsorship, the company received both exhibitor and

delegate passes and as far as the Manager was aware, the members of his/her team who attended the meeting did so using Leo passes. The Manager denied asking any member of his/her team to attend the meeting using an NHS pass.

In summary, following investigation, Leo found no evidence indicating that the matters described by the complainant had occurred. In these circumstances any breach of Clauses 15.5, 9.1 and 2 of the Code is denied.

PANEL RULING

Clause 15.5 stated that, in an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

The Panel did not have the role description of the complainant; however, it appeared to the Panel, on the evidence before it, that as part of the complainant's role he/she called on members of the health professions and other relevant decision makers in relation to the promotion of medicines and therefore he/she was a representative as defined by the Code and thus Clause 15.5 was relevant.

The Panel noted the complainant's allegations that he/she was asked by the Manager to use an NHS delegate badge at the 2019 Clinical Pharmacy Congress Meeting to save money and to gain valuable insights as such a badge would allow the complainant into areas that pharmaceutical staff could not access. The Panel further noted the complainant's comments that he/she did use an NHS delegate badge and had conversations with several Leo competitors at exhibitor booths about competitor products and he/she had discussions about Leo products with health professional delegates.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel queried the rigour of Leo's investigation; Leo's submission was limited to the Manager's version of events. It appeared to the Panel that other Leo employees were present at the congress, including two employees named by the complainant, and the Panel queried if Leo's investigation involved interviews with these other employees. Furthermore, in the Panel's view, confirmation of which pass the complainant used might have been ascertained by contacting the congress organisers for their records of attendees at sessions and the way in which attendees were registered; Leo made no submission in this regard. There was also no submission by Leo in relation to checking the company's financial records. Nonetheless, the Panel noted that the complainant bore the burden of proof.

There was no evidence before the Panel that the complainant was either instructed to use, or had used, an NHS delegate badge at the congress in question and that, in doing so, had misled exhibitors or delegates about his/her identity. Whilst noting the seriousness of the allegations, which in part related to the complainant's own alleged actions, the Panel considered, based on the lack of evidence, and the narrow allegation in relation to the delegate badge, that the complainant had not established that a breach of the Code had occurred as alleged and no breach of Clauses 15.5, 9.1 and 2 of the 2019 Code were ruled.

3 2019 British Association of Dermatologists (BAD) meeting

COMPLAINT

The complainant stated that the Manager invited him/her to attend the 2019 BAD meeting. The manager explained he/she wanted to keep his/her budget down and did not purchase a pass for the complainant. The complainant stated that to gain entry to this meeting, the Manager instructed him/her to approach colleagues and ask them to sneak out their pass once they were in. This exchange had to occur by the entrance by the security guards. The complainant stated that it felt uncomfortable, degrading and childish. The complainant stated that once he/she was in, the Manager invited him/her to attend competitor stands pretending that he/she still worked for the NHS. The complainant stated that he/she was asked to misrepresent him/herself yet again to gain competitor insights.

In response to a request for further information the complainant confirmed that he/she visited competitor company stands and pretended that he/she still worked for the NHS. The complainant stated that he/she visited seven different company stands.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 15.5, 9.1 and 2 of the 2019 Code in relation to this allegation.

RESPONSE

Leo stated that the complainant alleged that the Manager asked him/her to attend the 2019 BAD meeting in Liverpool on 3-5 July 2019, using a colleague's pass, in order to save on costs. During that meeting the Manager asked the complainant to attend competitor stands pretending that he/she still worked for the NHS, in order to gain competitor insights. The complainant complied with this request and attended the stands for seven different companies.

Leo stated that this allegation was investigated by Leo when it was raised by the complainant in October 2020 and no substantiating evidence was found. The Manager stated that he/she attended the BAD meeting together with one member of his/her team. Leo sponsored a symposium at the BAD meeting; all attendees from Leo were provided with exhibitor passes and the company was additionally allocated some delegate passes for the purposes of attendance at the symposium. The Manager denied asking anyone to attend competitor stands pretending that they still worked for the NHS.

In summary, following investigation, Leo found no evidence indicating that the matters described by the complainant had occurred. In these circumstances any breach of Clauses 15.5, 9.1 and 2 of the Code was denied.

PANEL RULING

The Panel noted the complainant's allegations that he/she was instructed by the Manager to gain entry to the 2019 BAD meeting by asking colleagues to share their passes and that once he/she was inside the meeting, the Manager asked him/her to attend competitor stands pretending that he/she still worked for the NHS; the complainant stated that he/she visited a number of competitor stands and pretended that he/she still worked for the NHS.

The Panel noted Leo's submission that the Manager attended the meeting together with one member of his/her team and that Leo had sponsored a symposium and all attendees from Leo were provided with exhibitor passes and the company was additionally allocated some delegate passes for the purposes of attendance at the symposium. The Manager denied asking anyone to attend competitor stands pretending that they still worked for the NHS.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities.

The Panel queried the rigour of Leo's investigation; Leo's submission was limited to the Manager's version of events. It appeared to the Panel that other Leo employees were present at the meeting, and the Panel queried if Leo's investigation involved interviews with other employees. There was also no submission by Leo in relation to checking the company's financial records and other records for how many exhibitor/delegate passes it received and how many Leo employees were present at the meeting.

Nonetheless, the Panel noted that the complainant bore the burden of proof. There was no evidence before the Panel that the complainant was either instructed to use, or had used, a colleague's pass to enter the meeting and in that regard no breach of Clause 9.1 of the 2019 Code was ruled.

The Panel noted the complainant's allegation that he/she had visited a number of competitor stands and pretended that he/she still worked for the NHS. The Panel considered that this was in effect a voluntary admission by the complainant of being deliberately misleading as to his/her identity and that of the company that he/she represented. Nonetheless, the complainant had provided no evidence that the alleged activity had occurred. In the Panel's view, it could not accept an admission from the complainant without any substantiating evidence. The Panel therefore ruled no breach of Clause 15.5 of the 2019 Code in that regard.

The Panel further considered that the complainant had not established that the manager had asked him/her to attend competitor stands pretending that he/she still worked for the NHS. Whilst noting the seriousness of the allegation, the Panel considered, based on the lack of evidence, that the complainant had not established that a breach of the Code had occurred and no breach of Clause 9.1 of the 2019 Code was ruled in that regard.

The Panel noted its rulings above of no breaches of the Code and consequently ruled no breach of Clause 2 of the 2019 Code.

4 Linking private payments to access to the NHS

COMPLAINT

The complainant stated that the Manager asked him/her to run an internal training session for the field team and that his/her initial idea was to involve a customer (NHS). The complainant alleged that he/she asked the Manager if he/she could arrange for an NHS employee to come in. The Manager was said to be initially keen until learning that the complainant had a named health professional in mind. When asked for an explanation, the Manager allegedly informed the complainant that the named health professional had been paid over £1,000 to run a

previous training session but had refused a request from one of the field team in his/her role in the NHS. The complainant stated that the Manager made it sound like the 2 events should be linked and this made the complainant feel very uncomfortable so he/she dropped the subject.

In response to a request for further information from the case preparation manager as to whether the complainant had approached the NHS employee about the training or was the conversation with the Manager prior to any discussion with the NHS employee, the complainant stated that a named person approached the NHS employee about the training and that this named person should be asked for the information provided to the NHS employee and whether he/she had to cancel arrangements and if so the reason for cancelling arrangements.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 9.1 and 2 of the 2019 Code in relation to this allegation.

RESPONSE

Leo noted that the complainant, alleged that while the Manager had initially seemed keen for the complainant to run a training session involving an NHS employee, this was only until he/she learned the identity of the NHS employee proposed by the complainant. When the complainant requested an explanation, the Manager informed him/her that the NHS employee in question had been paid over £1,000 to run a previous training session but had refused a request from one of the field team in his/her role in the NHS. The complainant said that the Manager 'made it sound like the 2 events should be linked'.

Leo stated that this allegation was investigated by Leo when it was raised by the complainant in October 2020 and no substantiating evidence was found. The Manager stated that he/she considered that an alternative NHS employee should be used for the training session, as the one proposed by the complainant had already provided insights. The Manager wished to obtain an alternative perspective and did not want to "over-use" the particular NHS employee. The Manager's reasons for preferring to use an alternative NHS employee, were not based on any refusal by the NHS employee proposed by the complainant in his/her role in the NHS. The NHS employee proposed by the complainant had been contracted by Leo since that time, although not by the Manager.

In summary, following investigation, Leo found no evidence indicating that the Manager had linked payments to NHS employees to their actions in their roles in the NHS. In these circumstances any breach of Clauses 9.1 and 2 of the Code was denied.

PANEL RULING

The Panel noted the complainant's allegation that the Manager did not want to contract the NHS employee proposed by the complainant for a field team training session because that particular NHS employee had been paid over £1,000 to run a previous training session but had still refused a request from one of the field team in his/her role in the NHS.

The Panel noted Leo's submission that the Manager stated that he/she considered that an alternative NHS employee should be used for the training session in question, as the one proposed by the complainant had already provided insights and the Manager wished to obtain an alternative perspective and did not want to 'over-use' this particular NHS employee.

The Panel was not an investigatory body as such; it made its rulings on the evidence provided by both parties and the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities. The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence.

It was not clear to the Panel what the purpose of the previous or planned training session was, nor what request the NHS employee in question had allegedly previously refused, nor what conversations were had between Leo and this NHS employee before the decision was made by Leo to use a different NHS employee for the planned training session in question.

The Panel had no evidence before it that the Manager had declined to contract with the NHS employee proposed by the complainant for the training session in question because he/she was previously paid by Leo for a service but subsequently refused a request from Leo in his/her role in the NHS. The Panel considered that the complainant had not established that a breach of the Code had occurred as alleged and no breach of Clauses 9.1 and 2 of the 2019 Code were ruled.

Complaint received **14 December 2020**

Case completed **13 January 2023**