CASE AUTH/2624/8/13

SENIOR PUBLIC HEALTH SPECIALIST v HRA PHARMA

Conduct of representative

A senior public health specialist alleged that the way in which a representative from HRA Pharma had communicated with her and one of her public health colleagues about the quality of the sexual health services provided in the local area and the training provided to pharmacists across the wider geographical area, breached the Code. The representative was concerned that ellaOne (ulipristal acetate), which was indicated for use in emergency contraception (EC), was not available locally through the pharmacy scheme for EC. An email from the representative to the complainant included:

> **'I appreciate there will be valid reasons for this decision, but it concerns me that because of the very active, and well promoted, pharmacy scheme for EC in … that women are actually receiving a poorer service than in other areas with a less well used pharmacy scheme. That may sound strange, but having spoken to GPs at meetings in ... most of them say they use very little emergency contraception as they refer girls to the pharmacy, where they can only get [a named product] unless they present after 72 hours (which very few do). … So, of the 3 options for women to receive emergency contraception, the 2 options (GPs and [contraception and sexual health services]) where they *could* be offered emergency contraception in line with Faculty guidance – ie to be offered all 3 choices – are being accessed less and less in favour of the one option – the pharmacy – where they can only be offered one choice. So what I am trying to point out, is that because [the local area] has been so good at promoting its pharmacy scheme, that is now the most chosen option to access EC, to the detriment of [contraception and sexual health services] and GPs, but it only offers the least effective method.**
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> **Having read the [Health and Wellbeing] Board draft strategy, I see there are plans to increase access to EC, but surely if there is such inequity of service, that should be improved as well. I have been discussing the possibility of including ellaOne in the pharmacy scheme for use before 72 hours with yourself and [a named person] before you for over 2 years now. In that time there have been potentially over 60 pregnancies each year that could have been prevented. …'**

In a written response to the representative, the complainant stated that she found the email concerning and offensive and considered that it made unsubstantiated claims about the quality of the service offered in the local area and the number of the unintended pregnancies in the city. The complainant acknowledged the apology she had received from the representative and her manager, and went on to state:

> **' … We take great offence regarding your allegations of a poorer service, working out with faculty guidance and increasing unintended pregnancies. Evidence from service providers demonstrates that the majority of women who attend for EC are offered a copper coil and data shows an increase of women choosing this method. For those who choose oral hormonal contraception the majority present within 72 hours and if for any reason they are unable to have [a named product] are referred on appropriately. Commissioned services are underpinned by specifications and [patient group directions] that are evidence based and meet with [National Institute for Health and Care Excellence] and Faculty guidance in addition we have demonstrable evidence that they are efficient and cost effective.**
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> **Assessment of need is on-going as is assessment of service provision. I am assured that women continue to have appropriate choice in where they go to receive emergency contraception as well as the contraceptive they receive.'**

In response to a request for further information by the Authority, the complainant noted that the representative had referred to discussing the matter with the head of service for the sexual health services in the provider trust. Although the complainant did not know the detail of that conversation or the content of the conversation with GPs, her interpretation from the email was that the representative had directed information on policy decisions to prescribers rather than commissioners. The representative had inferred that providers were concerned about EC provision, but this had never been raised directly with the complainant by any providers.

The complainant alleged that the claim about the prevention of over 60 unintended pregnancies if ellaOne had been used was over exaggerated and lacked objectively as there was no evidence. The complainant acknowledged that company trials and research had demonstrated that potential but it was potential rather than fact.

The complainant also complained about an email sent by the representative to a colleague which stated in relation to proposed meetings about pharmacy training:

> **'Although I have supported these meetings in the past, I don't think I can justify continuing to support them as national guidance came out around 18 months ago, and this training isn't in line with that guidance. Other areas around the country provide training which is in line with the guidance so it's not really ethical for me to support anything else.'**

The detailed response from HRA Pharma is given below.

The Panel noted that the representative had sent two emails to people involved in contraception and sexual health service provision. The first email was in response to a request for support for two EC training sessions for pharmacists. The representative declined and stated that it would not be ethical for her to support the proposed training as it was not in line with national guidance. In her second email which was to the complainant, the representative criticised local EC service provision and noted that because, locally, women were more likely to access EC via a pharmacy rather than from a GP or a contraception and sexual health service, they were only offered one named product rather than having the choice of three methods (including ellaOne). The representative was thus concerned that women in the area were 'actually receiving a poorer service than in other areas with a less well used pharmacy scheme'. The representative implied that by visiting a pharmacy, women were not being offered EC in line with Faculty [of Sexual & Reproductive Healthcare] guidance. The representative referred to a named product as 'the least effective medicine' and noted that in the two years she had unsuccessfully discussed the possibility of including ellaOne in the local pharmacy scheme, there had potentially been over 120 pregnancies which could have been prevented. Finally the representative stated that she would be happy to provide further information or a business case to help bring the local EC service provision in line with faculty guidance.

The Panel noted that in alleging a breach of the Code, the complainant had referred to a clause which dealt with advance notification of new products or product changes. The Panel noted that ellaOne was a licensed medicine. The email had not promoted the medicine outwith its marketing authorization or in a manner inconsistent with the particulars listed in the SPC. No breach of the Code was ruled in that regard.

The Panel noted that by sending the email to the complainant, the representative had, in effect, created and distributed her own promotional material which had not been certified prior to use; the representative had thus failed to maintain high standards. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted that the email to the complainant promoted ellaOne and included, *inter alia*, a claim that, had it been more widely used locally, potentially more than 120 pregnancies could have been prevented over a 2 year period. The Panel noted HRA's submission that that claim was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population in question. Nonetheless, it was not clear how the number of potentially preventable pregnancies had been calculated; there was no reference to the differences in absolute risk and there was no reference to the potential failure rate with ellaOne. Overall, the Panel considered that in the context in which it had been presented, the claim was misleading and exaggerated. Breaches of the Code were ruled as acknowledged by HRA Pharma.

The Panel considered that both emails disparaged local EC service provision. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted its rulings above and considered that sending the emails at issue was a serious breach of professionalism and that in doing so the representative had failed to maintain a high standard of ethical conduct. The representative had also failed to comply with all the relevant requirements of the Code. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted that a ruling of a breach of Clause 2 of the Code denoted particular censure. The Panel noted HRA Pharma's submission that the representative's email to the complainant had been an 'uncharacteristic lapse in professional judgement'. In the Panel's view both emails were unprofessional and disparaging and were such as to bring discredit upon, and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Upon appeal by HRA Pharma, the Appeal Board noted that the company had taken swift, positive action in response to the complaint and had acknowledged that what the representative had written was wholly unacceptable. In an unreserved email apology to the complainant, the representative acknowledged that her earlier email was 'inappropriate and unprofessional'. In his unreserved apology to the complainant, the general manager described the representative's email as 'inappropriate and appalling'. The national sales manager had also written to the complainant stating that the episode had clearly fallen below company standards. The Appeal Board considered that despite the fulsome and sincere apologies from the company and clear acknowledgement all round that the emails to the complainant and her colleague should never have been sent, the fact that they had, in itself, brought discredit upon, and reduced confidence in, the pharmaceutical Industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

A senior public health specialist complained about the conduct of a HRA Pharma UK & Ireland Ltd key account manager in the course of promoting ellaOne (ulipristal acetate) for emergency contraception (EC).

COMPLAINT

The complainant alleged that the way in which the representative in question had communicated with her and one of her public health colleagues about the quality of the sexual health services and the training provided to pharmacists across the geographical area, breached Clauses 3.2, 7.2, 7.10, 8.2 and 15.2 of the Code.

The complainant stated that the representative had sent her the following email on 26 July 2013:

'We met earlier this year to discuss including ellaOne (ulipristal acetate) in the pharmacy scheme, but I understand that since then it has been decided not [to] move forward on this yet.

I appreciate there will be valid reasons for this decision, but it concerns me that because of the very active, and well promoted, pharmacy scheme for EC in … that women are actually receiving a poorer service than in other areas with a less well used pharmacy scheme. That may sound strange, but having spoken to GPs at meetings in …, most of them say they use very little emergency contraception as they refer girls to the pharmacy, where they can only get [a named product] unless they present after 72 hours (which *very* few do). They could also go to … , but again, …, their use of emergency contraception is falling as girls just go the pharmacist, and indeed [a named pharmacy] give out around 250 units [of] emergency contraception each month, which is way in excess of what the C&SH [contraception and sexual health services] service give out. So, of the 3 options for women to receive emergency contraception, the 2 options (GPs and C&SH) where they *could* be offered emergency contraception in line with Faculty guidance – ie to be offered all 3 choices – are being accessed less and less in favour of the one option – the pharmacy – where they can only be offered one choice. So what I am trying to point out, is that because … has been so good at promoting its pharmacy scheme, that is now the most chosen option to access EC, to the detriment of C&SH and GPs, but it only offers the least effective method.

I looked at what proportion of all EC is given out as ellaOne in primary care across my territory, and as you can see … gives out one of the lowest proportions, with just over 1 out of every 50 women getting ellaOne. That is because the vast majority of women use pharmacy as their source of EC … .

Having read the [Health and Wellbeing] Board draft strategy, I see there are plans to increase access to EC, but surely if there is such inequity of service, that should be improved as well. I have been discussing the possibility of including ellaOne in the pharmacy scheme for use before 72 hours with yourself and … for over 2 years now. In that time there have been potentially over 60 pregnancies *each year* that could have been prevented. I appreciate it has been a time of huge change, but teenage conceptions remain a problem, and other areas are now reviewing their pharmacy schemes as part of the overall NHS structural change and bringing them in line with Faculty guidance. If I can be of any assistance in helping that happen in …, I'd be happy to provide further information, or a business case.'

In a written response to the representative, the complainant stated that she found the email concerning and offensive and considered that it made unsubstantiated claims about the quality of the service offered in … and the number of the unintended pregnancies. The complainant acknowledged the apology she had received from the representative and her manager, and went on to state:

'As the lead commissioner for sexual health services in … I believe that we currently provide an excellent service to all who present for services, although I accept that there is always room for improvement. As you know I work closely with the provider service leads in … as well as my public health colleagues across [the area] and I have shared your email with them. We take great offence regarding your allegations of a poorer service, working out with faculty guidance and increasing unintended pregnancies. Evidence from service providers demonstrates that the majority of women who attend for EC are offered a copper coil and data shows an increase of women choosing this method. For those who choose oral hormonal contraception the majority present within 72 hours and if for any reason they are unable to have [a named product] are referred on appropriately. Commissioned services are underpinned by specifications and [patient group directions] that are evidence based and meet with [National Institute for Health and Care Excellence] and Faculty guidance in addition we have demonstrable evidence that they are efficient and cost effective.

Assessment of need is on-going as is assessment of service provision. I am assured that women continue to have appropriate choice in where they go to receive emergency contraception as well as the contraceptive they receive.'

In response to a request for further information by the Authority, the complainant noted, with regard to Clause 3.1, that the representative had referred to discussing the matter with the head of service for the sexual health services in the provider trust. Although the complainant did not know the detail of that conversation or the content of the conversation with GPs, her interpretation from the email was that the representative had directed information on policy decisions to prescribers rather than commissioners. The representative had inferred that providers were concerned about EC provision, but this had never been raised directly with the complainant by any providers.

With regard to Clause 7.10, the complainant alleged that the claim about the prevention of over 60 unintended pregnancies if ellaOne had been used was over exaggerated and lacked objectively as there was no evidence of that being the case. The complainant acknowledged that company trials and research had demonstrated that potential but it was potential rather than actual fact.

The complainant also complained about an email sent by the representative to a colleague which stated in relation to proposed meetings about pharmacy training:

'Although I have supported these meetings in the past, I don't think I can justify continuing to support them as national guidance came out around 18 months ago, and this training isn't in

line with that guidance. Other areas around the country provide training which is in line with the guidance so it's not really ethical for me to support anything else.'

When writing to HRA Pharma, the Authority asked that, in addition to the clauses cited by the complainant, it also respond in relation to Clauses 2 and 9.1.

RESPONSE

HRA Pharma noted that the representative concerned was a contract sales representative. In responding to this complaint, HRA Pharma had liaised closely with the contract sales company.

The email sent by the representative and the cause of this complaint contravened both HRA Pharma's and the contract sales company's internal procedures and training pertaining to the Code and specifically instructions about communications with health professionals. In the light of this contravention, the representative was immediately suspended pending an investigation by the contract sales company, which had resulted in formal disciplinary action.

Both HRA Pharma and the contract sales company treated adherence to the Code with high importance, and both had taken immediate corrective and augmentative measures. Both companies deeply regretted that despite full training and clearly defined operating procedures the representative had acted such that a health professional had complained.

With regard to Clause 3.2, HRA Pharma stated that whilst it did not seek to minimise the breaches of the Code inherent in the email, the claims made were not out of line with the marketing authorization and summary of product characteristics (SPC), which specifically contained a table of odds ratios demonstrating that ellaOne was significantly more effective than a named product over the period 0 – 72 hours. Additionally the claims solely pertained to the use of the medicine as an emergency contraceptive which was clearly within the scope of the SPC.

In her letter, the complainant referred to elements of the supplementary information to Clause 3.1 which concerned advance notification of new products. EllaOne had been available and licensed since 2009, so there was no reason why discussions with clinical leads could not be conducted.

In conclusion HRA Pharma denied a breach of Clause 3.2.

HRA Pharma noted that the email sent by the representative contained promotional claims, did not contain prescribing information and had not been through the company's approval and certification process and therefore was not certified for release. Claims had been made without providing references (and proper context) to substantiate them. The claim of a possible additional 60 pregnancies prevented was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population, but this calculation was not adequately explained in the email and there was also no reference to the differences in absolute risk, thus the potential benefit was presented without proper contextual balance. Additionally there was no mention of the potential failure rate of ellaOne ie number of pregnancies that would still occur, hence HRA Pharma accepted that the email had breached Clauses 7.2 and 7.10.

The email contravened the internal HRA Pharma Field Briefing document, 'Communication with [health professionals] via e mail' and also was in breach of the contract sales company's standard operating procedure (SOP), 'COM 008 – Use of e-mail and other methods of communication by field force'. Copies of these procedures were provided. HRA Pharma and the contract sales company believed that these procedures represented good practice in relation to the management of communications between sales people and health professionals.

HRA Pharma acknowledged that the email, at best, was clumsily worded and at worst was plainly pejorative in its description of the emergency contraceptive services available in Newcastle. HRA Pharma accepted breaches of Clauses 8.2 and 15.2.

HRA Pharma noted that the representative had spent many years in the pharmaceutical industry, mostly as a sales representative. She passed her ABPI examination with distinction and had, until now, enjoyed an unblemished record. Given this, her maturity and also the training she had received as well as the understanding demonstrated during that training, it was hard to understand why she wrote the email at all. HRA Pharma was certain that it was a momentary lapse of professional judgment which was entirely out of character. HRA Pharma accepted a breach of Clause 9.1 in that the representative failed to maintain high standards at all times. HRA Pharma referred to its comments with regard to Clause 15.2 and held up her previous unblemished record as mitigation.

Given the overriding importance of Clause 2, HRA Pharma had outlined the most pertinent points so that this incident, which appeared to be an uncharacteristic lapse in professional judgment by one of its most experienced and trusted representatives, could be placed in its proper context.

Both HRA Pharma and the contract sales company treated adherence to the Code with high importance, and both had extensive training and robust procedures in place to ensure that their representatives complied with the Code. On becoming aware of this complaint, both companies took immediate corrective actions and instigated further measures. Details were provided.

Contract Sales Company

Investigation:

- The representative was suspended whilst it undertook an internal investigation. This involved undertaking an investigation with the representative, the analysis of training records and validations on the company's internal SOPs (including – Use of email and other methods of communication by field force), other internal SOPs and the Code. The representative was up-to-date with training on the Code as part of the company-wide refresher training.

Corrective action:

- A disciplinary procedure was completed
- The representative would undergo further refresher training on both the Code and relevant SOP

Augmentative actions:

- Within the next month the company would review its SOP to ensure it remained fit for purpose and all directions were being adhered to by the relevant employees
- Within the next month remote training would be provided to the entire field force to highlight the importance of adhering to the SOP and clearly outline the implications of not doing so
- Managers would be required to discuss the SOP with each of their reports during the next scheduled field visit and this would be documented in the field visit database.

HRA Pharma

- The representative and her HRA Pharma line manager had formally apologised in writing to the complainant
- A letter had been sent to the complainant to apologise on behalf of HRA Pharma, and also to let her know that it had taken appropriate corrective actions
- HRA Pharma's internal training records clearly showed the training given regarding the Code and specifically recorded the team's, and specifically the representative's, acceptance and understanding of the email protocol
- HRA Pharma had re-issued and strengthened its guidance for representatives on email communication and would implement further Code training at the cycle briefing in early September.

Whilst HRA Pharma and the contract sales company were deeply disappointed that this had happened they were confident, having reviewed procedures and the training provided to representatives by both companies, that they had the appropriate controls in place to avoid, as far as was possible, such occurrences in the future.

In conclusion, an experienced and trusted representative had flagrantly ignored clear written instructions and acted in contravention of her documented training on the Code, received from both companies. This action was completely out of character for her and therefore completely arbitrary and unforeseeable. Both companies had acted decisively and urgently to manage the situation and HRA Pharma had provided a timely and unreserved apology to the complainant. Given the circumstances as set out, HRA Pharma did not accept that a ruling of a breach of Clause 2 was warranted.

PANEL RULING

The Panel noted that the representative had sent two emails to people involved in contraception and sexual health service provision. The first email was in response to a request for support for two emergency contraception (EC) training sessions for pharmacists. The representative declined and stated that it would not be ethical for her to support the proposed training as it was not in line with national guidance. In her second email which was to the complainant, a public health specialist, the representative criticised local EC service provision and noted that because, locally, women were more likely to access EC via a pharmacy rather than from a GP or a contraception and sexual health service, they were only offered one product rather than having the choice of three methods (including ellaOne). The representative was thus concerned that women in the area were 'actually receiving a poorer service than in other areas with a less well used pharmacy scheme'. The representative implied that by visiting a pharmacy, women were not being offered EC in line with Faculty [of Sexual & Reproductive Healthcare] guidance. The representative referred to a named product as 'the least effective medicine' and noted that in the two years she had unsuccessfully discussed the possibility of including ellaOne in the local pharmacy scheme, there had potentially been over 120 pregnancies which could have been prevented. Finally the representative stated that she would be happy to provide further information or a business case to help bring the local EC service provision in line with faculty guidance.

The Panel noted that in alleging a breach of Clause 3.2, the complainant had referred to part of the supplementary information to Clause 3.1 which dealt with advance notification of new products or product changes. The Panel noted that ellaOne was a licensed medicine. The email to the complainant only referred to ellaOne as an emergency contraceptive and in that regard had not promoted the medicine outwith its marketing authorization or in a manner inconsistent with the particulars listed in the SPC. No breach of Clause 3.2 was ruled.

The Panel noted that by sending the email to the complainant, the representative had, in effect, created and distributed her own promotional material; the email had not been certified prior to use in accordance with Clause 14. The Panel considered that the representative had thus failed to maintain high standards. A breach of Clause 9.1 was ruled as acknowledged by HRA Pharma.

The Panel noted that the email to the complainant promoted ellaOne and included, *inter alia*, a claim that, had it been more widely used locally, potentially more than 120 pregnancies could have been prevented over a 2 year period. The Panel

noted HRA's submission that that claim was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population in question. Nonetheless, it was not clear how the number of potentially preventable pregnancies had been calculated; there was no reference to the differences in absolute risk and there was no reference to the potential failure rate with ellaOne. Overall, the Panel considered that in the context in which it had been presented, the claim was misleading and exaggerated. Breaches of Clauses 7.2 and 7.10 were ruled as acknowledged by HRA Pharma.

The Panel considered that both emails disparaged local EC service provision. A breach of Clause 8.2 was ruled as acknowledged by HRA Pharma.

The Panel noted its rulings above and considered that sending the emails at issue was a serious breach of professionalism and that in doing so the representative had failed to maintain a high standard of ethical conduct. The representative had also failed to comply with all the relevant requirements of the Code. A breach of Clause 15.2 was ruled as acknowledged by HRA.

The Panel noted that a ruling of a breach of Clause 2 of the Code denoted particular censure. The Panel noted HRA Pharma's submission that the representative's email to the complainant had been an 'uncharacteristic lapse in professional judgement'. In the Panel's view both emails were unprofessional and disparaging and were such as to bring discredit upon, and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL FROM HRA PHARMA

HRA Pharma appealed on the grounds that the particular censure inherent in a ruling of a breach of Clause 2 was not appropriate in the circumstances as the events, and its response to them, had neither reduced confidence in the industry nor brought discredit upon it. Indeed, HRA Pharma submitted that the open way in which it had acknowledged the mistakes made by a single representative, and had addressed them, actually enhanced the reputation of the industry.

HRA Pharma submitted that the ruling might set a precedent that if the Panel judged the breaches to be of significant severity then a breach of Clause 2 was ruled regardless of a company's culture and governance frameworks and any actions it took to acknowledge and prevent a repetition or rectify the situation.

In this instance HRA Pharma submitted that it could not conceive of any further action it could reasonably be expected to have taken and it outlined these actions briefly as follows:

- HRA Pharma employed only experienced representatives via industry respected suppliers,
- Representatives received full and regular training on the Code from the contract sales company and HRA Pharma
- Both HRA Pharma and the contract sales company had specific policies and guidance in place about email communication with health professionals when these events took place
- On becoming aware of the emails, an unreserved written apology was issued by the representative in question
- A further written apology was sent by the responsible line manager
- Further to this, a comprehensive written apology was sent by the managing director which emphasised HRA Pharma's values and how this incident had fallen well below them
- These actions were taken because HRA Pharma did not tolerate disrespectful communication with customers, and held adherence to the Code as the highest priority. HRA Pharma decided to take those actions before it knew that a formal complaint had been made, although there was some overlap in implementation. Ongoing follow-up would also have been taken but for the need to go through the due process of the formal complaint. HRA Pharma's commitment to follow-up remained however, and on completion of the appeal process it would contact the complainant again to de-brief as she requested in response to the managing director's letter
- The complainant was also told about the internal actions taken and that the company had treated this matter responsibly and with due priority
- After an initial investigation into the circumstances, the representative was suspended pending a disciplinary investigation
- This investigation resulted in formal disciplinary action and the representative received further training on the Code. The entire HRA Pharma team also received further specific training on the requirements for email communication with health professionals
- On receipt of the complaint HRA Pharma assessed the evidence and conceded that breaches of Clauses 7.2, 7.10, 8.2, 9.1 and 15.2 had occurred and stated the rationale for each, which demonstrated a proper responsibility towards the Code and the complainant.

HRA Pharma thus submitted that it had acted in a responsible and proper manner, fully in keeping with responsible reasonable expectations placed upon the industry and, in doing so, had in fact acted to augment the credibility and confidence in the industry in the face of a justifiable complaint. Surely the best measure of a company's credibility (and the industry's) was how it acted to ensure, as far was possible, compliance with the Code at all times and to identify and rectify any transgressions.

COMMENTS FROM THE COMPLAINANT

The complainant stated that she was happy with the decisions made and although she had not cited a breach of Clause 2 she was reassured that the Panel considered that the representative's behaviour was in breach of that clause.

APPEAL BOARD RULING

The Appeal Board noted that HRA Pharma had taken swift, positive action in response to the complaint and had acknowledged that what the representative

had written was wholly unacceptable. In an unreserved email apology to the complainant, the representative acknowledged that her earlier email was 'inappropriate and unprofessional'. In his unreserved apology to the complainant, the general manager described the representative's email as 'inappropriate and appalling'. The national sales manager had also written to the complainant stating that the episode had clearly fallen below company standards. The Appeal Board considered that despite the fulsome and sincere apologies from the company and clear acknowledgement all round that the emails to the complainant and her colleague should never have been sent, the fact that they had, in itself, brought discredit upon, and reduced confidence in, the pharmaceutical Industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Complaint received **31 July 2013**

Case completed **19 December 2013**