

HEALTH PROFESSIONAL CONSULTANT TO A PHARMACEUTICAL COMPANY/DIRECTOR v PFIZER

Online advertisement for a meeting

A complaint was received in a private capacity from a health professional who stated that he/she worked as a consultant to a pharmaceutical company. It had previously been decided, following consideration by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for intercompany complaints, the employing company would be named in the report. The complainant would be advised that this would happen and be given an opportunity to withdraw the complaint.

The principles set out above were applied to this complaint. Consultancy status should not be used to circumvent the normal rules for inter-company complaints.

The complainant was advised that if he/she wished to proceed with the complaint in a private capacity Novartis would be named in the case report; and the respondent company would be informed of his/her professional status and the connection with pharmaceutical companies. The complainant so agreed.

As part of the complaint concerned an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

The complaint concerned an advertisement published in Pulse today.co.uk inviting readers to a Pfizer meeting to be held in January 2017. The invitation was headed 'The ultimate stop smoking roadshow 2017 3 Events Across the UK' and details of a relevant website were given. The complaint also concerned two invitations sent by email in December 2016 and January 2017 to attend road show events.

The complainant stated that although there was a statement that Pfizer had funded the programme (displayed on the website and the emails but too blurry to read on the advertisement), it was not clear where editorial control resided. The emails and the advertisement all stated that Pfizer products might be mentioned, but the complainant could find no link to the relevant prescribing information. There was no clear prominent statement as to where it could be found. As a consequence, there was no adverse event statement. The description of 'ultimate stop smoking roadshow' was inappropriate language and, given it was taking place in January, might not be the case by the end of the year – if any event could be described as

'ultimate' – it was not the most appropriate taste and failed to recognise the professional standing of the audience.

Given the lack of clarity on the emails, the advertisement and the website, the complainant was concerned regarding materials that were used on the day. Had these too failed to have prescribing information where appropriate? The complainant had no knowledge of these, but was concerned that the same issues might be present.

In a subsequent email, the complainant stated that he/she noted that Case AUTH/2818/1/16 mentioned disguised promotion and lack of clarity of declarations of sponsorship. The complainant requested that this matter also be reviewed to determine whether Pfizer had complied with its undertaking given in that case.

The detailed response from Pfizer is given below.

The Panel examined the invitations at issue. The advertisement published online in Pulse was headed 'THE ULTIMATE STOP SMOKING ROADSHOW 2017' followed by '3 EVENTS ACROSS THE UK'. The date of the meeting was given followed by 3 bullet points: Meeting the challenges; Clinical study news; and KOL-led presentations. The Panel was unsure why the declaration statement in the advertisement provided by the complainant was blurry but noted Pfizer's submission that the online advertisement was clear and legible. The statement read 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics' followed by the Pfizer logo. The Panel also noted the references to Pfizer in the emails.

The Panel considered that Pfizer's role in the initiation and funding of the program had been made clear. No breach was ruled in relation to each email and the online invitation published in Pulse.

The Panel noted that there was no direct or implied mention of any medicine in the invitation and emails. Recipients would be clear that Pfizer's meeting would include treatment strategies and 'may include reference to Pfizer's medicines relevant to the agenda topics'. The Panel considered that whilst it might be prudent to provide prescribing information with the invitations as the invitation did not promote any specific Pfizer medicines, it was not a breach of the Code not to do so. The adverse event reporting requirements were thus not triggered. The Panel ruled no breach.

The Panel noted that 'ultimate', as used in the material in question, was used to describe the event

rather than a medicine. The Panel did not consider that the term 'ultimate' was a direct or indirect claim for a medicine on the materials at issue. The Panel thus ruled no breaches of the Code.

The Panel considered that, on balance, describing the series of meetings on the three items at issue as 'the ultimate stop smoking roadshow' did not recognise the special nature of medicines and the professional standing of the audience and a breach was ruled.

The Panel noted the complainant's concern that materials used on the day failed to have prescribing information where appropriate. The Panel noted that the complainant had not seen the materials but posed a series of questions about them and a hypothetical scenario. The Panel noted Pfizer's submission that the audience was made aware of the availability of prescribing information as necessary from the outset of the presentation and, in addition, material with prescribing information was available to attendees at the meeting. The Panel reviewed the slides and noted that although Pfizer medicines were included, no prescribing information was given nor did the slides state where such could be found.

[Post meeting note. On completion of this case Pfizer advised that of the presentations, all of which stated 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics', those presentations that referred to Champix (varenicline tartrate) included reference to the availability of its prescribing information at the meeting].

The Panel noted that it was an established principle that prescribing information for a presentation should either be part of it or be otherwise available to each delegate, a leavepiece provided to each delegate would suffice in this regard. If prescribing information formed part of the presentation in the absence of alternative formats, it should be displayed such that the audience had sufficient time to consider it. The Panel considered it prudent and good practice to include prescribing information on presentations at meetings even if the prescribing information was also made available on a leavepiece or similar. The Panel noted the nature of the allegation and Pfizer's explanation above about the availability of prescribing information at the meeting and therefore ruled no breach of the Code.

The Panel noted its rulings above and overall did not consider that high standards had not been maintained and therefore ruled no breach in that regard.

The Panel noted the complainant's further allegation that Pfizer might not have complied with its undertaking in Case AUTH/2818/1/16. In that case, the Panel considered that it was not sufficiently obvious at the outset that an email invitation to a Sayana Press webinar, sent by a third party event organiser on Pfizer's behalf, was promotional and from a pharmaceutical company. The Panel considered the promotional nature of that email

was disguised and a breach was ruled. Turning to this case, Case AUTH/2931/1/17, the Panel noted its rulings above that the declaration of Pfizer's role in the initiation and funding of the programme was clear. The Panel did thus not consider that Pfizer had failed to comply with its undertaking given in Case AUTH/2818/1/16. The Panel ruled no breach of the Code including Clause 2.

The complainant stated at the time of submitting the complaint that he/she was a health professional who worked as a consultant to Novartis. It had previously been decided, following consideration by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for inter-company complaints, the employing company would be named in the report. The complainant would be advised that this would happen and be given an opportunity to withdraw the complaint.

This issue came to the fore many years ago when an employee of a pharmaceutical research company complained in a private capacity about a journal advertisement issued by GlaxoSmithKline UK Ltd (Case AUTH/1498/7/03). In Case AUTH/1498/7/03 it was decided that the pharmaceutical research company would be named in the case report whilst making it clear that the complaint was made in a private capacity.

The case preparation manager decided that principles set out above would apply to consultants. Consultancy status should not be used to circumvent the normal rules for inter-company complaints.

The complainant was advised that if he/she wished to proceed with the complaint in a private capacity Novartis would be named in the case report; and the respondent company would be informed of his/her professional status and the connection with pharmaceutical companies. The complainant so agreed.

Novartis stated that it had no knowledge of or involvement in, the complaint and did not know the complainant's identity.

As part of the complaint concerned an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

The complaint concerned an advertisement published in Pulse today.co.uk inviting readers to a Pfizer meeting to be held in January 2017. The invitation was headed 'The ultimate stop smoking roadshow 2017 3 Events Across the UK' and details of a relevant website were given. The complaint also concerned two invitations sent by email in December 2016 and January 2017 to attend road show events.

COMPLAINT

The complainant stated that although there was a statement that Pfizer had funded the programme

(displayed on the website and the emails but too blurry to read on the advertisement), it was not clear where editorial control resided. The emails and the advertisement all mentioned that Pfizer products might be mentioned, but the complainant could find no link to the prescribing information for any products that might be mentioned. There was no clear prominent statement as to where it could be found. As a consequence, there was no adverse event statement. The description of 'ultimate stop smoking roadshow' was inappropriate language for an event aimed at health professionals and, given it was taking place in January, might not be the case by the end of the year – if any event could be described as 'ultimate' – it was not the most appropriate taste and failed to recognise the professional standing of the target audience.

Given the lack of clarity on the emails, the advertisement and the website, the complainant was concerned regarding materials that were used on the day. Had these too failed to have prescribing information where appropriate? Did the fact that the slides might have product information indicate that the speakers had provided their own slides and Pfizer was not aware of what the content was to be? The emails indicated that there had been meetings previously organised. The complainant had no knowledge of these, but was concerned that the same issues might be present.

In a subsequent email, the complainant stated that he/she noted that Case AUTH/2818/1/16 mentioned disguised promotion and lack of clarity of declarations of sponsorship. The complainant requested that this matter also be reviewed to determine whether Pfizer had complied with its undertaking given in that case.

Pfizer was asked to respond to the requirements of Clauses 4.1, 4.9, 7.10, 9.1, 9.2 and 9.10 of the Code in relation to the smoking cessation materials and Clauses 2, 9.1 and 29 in relation to the alleged breach of undertaking.

RESPONSE

Pfizer stated that it had spoken with the medical director at Novartis. Novartis had no knowledge of the complaint and did not support it.

Pfizer strongly refuted all the allegations.

Pfizer's submitted that its involvement in the meeting was prominently declared on all the materials. The wording 'this program was initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics' was prominently shown alongside the Pfizer logo on the website, the invitation published in Pulse and email invitations to ensure that the promotional nature of the meeting was clear. As such, responsibility for the meeting and related materials, including meeting content, was with Pfizer. The meeting content had been appropriately certified; there was no ambiguity regarding editorial control as Pfizer was responsible for the materials and content of the meeting.

In reference to the comment that the advertisement was too blurry to read, this was not the case with the actual online advertisement which was clear and legible.

Pfizer submitted that as the emails, the invitation published in Pulse and registration website did not contain any mention of specific product or promotional content, there was no requirement for prescribing information or adverse event reporting information to be provided.

The slides for the meeting had been certified as required under the Code and where Pfizer medicines were mentioned, the audience was made aware of the availability of prescribing information as necessary from the outset of the presentation. In addition, material with prescribing information was available to attendees at the meeting.

Pfizer submitted that the use of the word 'ultimate' was not a breach of the Code, as this was not used in relation to a product and was not making any claim about a product but rather aimed to convey to the reader the breadth of coverage and high quality of the faculty and meeting content. However, given the concern raised by the complainant, Pfizer intended to use alternative wording in future if similar meetings took place.

Pfizer submitted that previous meetings and associated materials in the same series of events were developed and conducted to the same high standards with full compliance with the Code.

Pfizer denied a breach of Clauses 4.1, 4.9, 7.10, 9.1, 9.2 and 9.10.

As mentioned above, Pfizer's involvement in the meeting was prominently declared on all the materials. The wording 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics' was prominently shown alongside the Pfizer logo on the website, advertisement and email invitations to ensure that the promotional nature of the meeting was clear. The opening slides shown at the meeting had the same wording and logo to ensure delegates were in no doubt of Pfizer's involvement in the meeting. Pfizer submitted that it had fully complied with the above mentioned undertaking and had not breached Clauses 2, 9.1 and 29.

In summary, Pfizer disagreed with all of the complainant's allegations and was of the opinion that it had fully complied with the Code and maintained high standards throughout.

PANEL RULING

The Panel examined the invitations at issue. The advertisement published online in Pulse was headed 'THE ULTIMATE STOP SMOKING ROADSHOW 2017' followed by '3 EVENTS ACROSS THE UK'. The date of the Leeds meeting was given followed by 3 bullet points: Meeting the challenges; Clinical study news; and KOL-led presentations. The Panel was unsure why the declaration statement in the advertisement

provided by the complainant was blurry but noted Pfizer's submission that this was not the case with the actual online advertisement which was clear and legible. The statement read 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics' followed by the Pfizer logo.

The December 2016 email stated the complainant's name followed by 'your invitation to: The Ultimate Stop Smoking Roadshow 2017'. The January 2017 email also stated the complainant's name followed by 'only a few places left for the Ultimate Stop Smoking Roadshow'. The subject heading of both was 'The Ultimate Stop Smoking Roadshow 2017' and the body of each was headed 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics' adjacent to the Pfizer logo. This was followed on both emails by a highlighted box which included the statement 'THE ULTIMATE STOP SMOKING ROADSHOW 2017' above registration details. The December 2016 email stated that presentations led by UK smoking cessation KOLs would include: The nature of nicotine addiction; How can we reduce smoking prevalence?; and smoking cessation options – including latest developments. Details of the three half-day events being held across the country were also provided. The January 2017 email did not provide details of the presentations but stated 'Remember ... Each Roadshow event will reveal stimulating, up-to-date facts and expert opinions, plus the latest clinical study news and a comprehensive examination of the challenges faced by HCPs'. The website address for the roadshow was given and each email was signed by an events agency. At the bottom of each it was stated that the event was in association with Pulse, Nursing in Practice and the Pharmacist. It was endorsed by the Advisor. A statement towards the bottom of each read 'All meeting costs, including speaker honoraria, have been covered by Pfizer'.

The supplementary information to Clause 9.10, Declaration and Sponsorship, stated, *inter alia*, that the wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company's involvement and influence over the material. The Panel noted Pfizer's submission that its involvement in the meeting was prominently declared on all the materials including the website, the invitation published in Pulse and email invitations to ensure that the promotional nature of the meeting was clear. The Panel further noted Pfizer's submission that it was responsible for the meeting and related materials. The Panel noted that Pfizer's role was clearly stated on the invitation published in Pulse. In relation to the emails, the company logo and declaration of its involvement appeared prominently in the body of the email as the heading to each. The Panel considered that Pfizer's role in the initiation and funding of the program had been made clear. No breach of Clause 9.10 was ruled in relation to each email and the online invitation published in Pulse.

The Panel noted that there was no direct or implied mention of any medicine in the invitation and emails.

Recipients would be clear that Pfizer's meeting would include treatment strategies and 'may include reference to Pfizer's medicines relevant to the agenda topics'. The Panel considered that whilst it might be prudent to provide prescribing information with the invitations as the invitation did not promote any specific Pfizer medicines, it was not a breach of the Code not to do so. The adverse event reporting requirements were thus not triggered. The Panel ruled no breach of Clauses 4.1 and 4.9 in relation to each email and the online invitation published in Pulse.

The Panel noted the complainant's allegation that 'ultimate stop smoking roadshow' was inappropriate language for an event aimed at health professionals and failed to recognise the professional standing of the target audience. The Panel noted that, *inter alia*, exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they related to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this could be substantiated. The Panel noted that 'ultimate', as used in the online advertisement and two emails in question, was used to describe the event rather than a medicine. The Panel did not consider that the term 'ultimate' was a direct or indirect claim for a medicine on the materials at issue. The Panel noted that there was no allegation about any subsequent use of the term at the events at issue. The Panel thus ruled no breach of Clause 7.10.

The Panel noted the requirement of Clause 9.2 that materials and activities must recognise the special nature of medicines and the professional standing of the audience and must not be likely to cause offence. The Panel noted Pfizer's submission that 'ultimate' aimed to convey to the reader the breadth of coverage and high quality of the faculty and meeting content but that it intended to use alternative wording in future if similar meetings took place. The Panel considered that the breadth of coverage etc could have been conveyed in other ways. The Panel considered that, on balance, describing the series of meetings on the three items at issue as 'the ultimate stop smoking roadshow' did not recognise the special nature of medicines and the professional standing of the audience and a breach of Clause 9.2 was ruled.

The Panel noted the complainant's concern that materials used on the day failed to have prescribing information where appropriate. The Panel noted that the complainant had not seen the materials but posed a series of questions about them and a hypothetical scenario. The Panel noted Pfizer's submission that the audience was made aware of the availability of prescribing information as necessary from the outset of the presentation and, in addition, material with prescribing information was available to attendees at the meeting. The Panel reviewed the slides provided by Pfizer and noted that although Pfizer medicines were included, no prescribing information was given nor did the slides state where such could be found.

[Post meeting note. On completion of this case Pfizer advised that of the presentations, all of which stated 'This program is initiated and funded by Pfizer and may include reference to Pfizer medicines relevant to the agenda topics', those presentations that mentioned Champix (varenicline tartrate) did include reference to the availability of its prescribing information at the meeting].

The Panel noted that in relation to presentations delivered at a meeting, it was an established principle that prescribing information for a presentation should either be part of it or be otherwise available to each delegate, a leavepiece provided to each delegate would suffice in this regard. If prescribing information formed part of the presentation in the absence of alternative formats, it should be displayed such that the audience had sufficient time to consider it. The Panel considered it prudent and good practice to include prescribing information on presentations at meetings even if the prescribing information also was made available on a leavepiece or similar. The Panel noted the nature of the allegation and Pfizer's explanation above about the availability of prescribing information at the meeting and therefore ruled no breach of Clause 4.1.

The Panel noted that all complainants had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The Panel noted that in this case the complainant had made

a general statement regarding similar issues with previously organised meetings but had not identified the meetings or submitted any detailed reasons or allegations. Due to the lack of any specific *bona fide* allegations, the Panel did not consider this matter.

The Panel noted its rulings above and overall did not consider that high standards had not been maintained and therefore ruled no breach of Clause 9.1.

The Panel noted the complainant's further allegation that Pfizer might not have complied with its undertaking in Case AUTH/2818/1/16. In that case, the Panel considered that it was not sufficiently obvious at the outset that an email invitation to a Sayana Press webinar, sent by a third party event organiser on Pfizer's behalf, was promotional and from a pharmaceutical company. The Panel considered the promotional nature of that email was disguised and a breach of Clause 12.1 was ruled. Turning to this case, Case AUTH/2931/1/17, the Panel noted its rulings above that the declaration of Pfizer's role in the initiation and funding of the program was clear. The Panel did thus not consider that Pfizer had failed to comply with its undertaking given in Case AUTH/2818/1/16. The Panel ruled no breach of Clause 29 and subsequently no breach of Clauses 9.1 and 2.

Complaint received	16 January 2017
Case completed	27 June 2017