

ANONYMOUS, NON-CONTACTABLE v ALMIRALL

Arrangements for a meeting

An anonymous, non-contactable ex-employee complained about the arrangements for a meeting, 'Psoriasis Management of Patients OverTime – PsoMOT', organised by Almirall Spain to which UK doctors were invited to attend.

The complainant alleged that Almirall UK selected and invited UK doctors to attend the lavish meeting in Berlin on Friday, 26 October 2018 based on their prescribing of Almirall products.

The meeting was attended by Almirall UK representatives and on Friday, 26 October guests flew in for a lavish dinner. There was no educational content on that day as per the invite.

On Saturday, 27 October there was a number of promotional presentations on Almirall's product from various paid speakers as per the agenda. In the evening a second lavish dinner with a music band and cabaret dancers was held at a named venue.

On Sunday there were more presentations on the company's product and the meeting finished at noon. A three course sit down lunch was provided.

The detailed response from Almirall is given below.

The Panel noted that there was no evidence that the UK invitees were chosen on the basis of their prescribing of Almirall products. The briefing to the representatives set out the criteria and the nominations were reviewed by senior employees in marketing and medical. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that the prescribing of Almirall products was the reason for inviting the health professionals. Thus, no breach of the Code was ruled.

In relation to the allegations about the hospitality, the Panel noted that the limits in the host country code would apply. The limit in the German Code was €60 per meal including VAT.

According to the agenda for the meeting as provided by Almirall, it started at 08.15 on Saturday, 27 October and finished at 16.30 with 30 minutes for a morning coffee break and 90 minutes for lunch. The agenda for Sunday, 28 October started at 09.00 where delegates could choose to attend two sessions of parallel workshops followed by 30 minutes conclusion and wrap up finishing the meeting at 11.30. There was no mention on the agenda of the dinners on the Friday and Saturday evenings, nor of the lunch on the Sunday. The meeting schedule provided by the complainant had more detail about the arrangements including those for the dinners on Friday and Saturday and the lunch on Sunday.

The various groups had dinner by country at different restaurants on the Friday evening and all the delegates had dinner together on the Saturday evening, sitting in country groups.

The Panel noted that the cost of the meal on the Friday evening for UK delegates including drinks and taxes was within the limits of the German Code requirements as was cost of the dinner on the Saturday evening.

There was no agenda, presentations nor educational content provided on the Friday as alleged. The Panel considered that it was not necessarily unacceptable to offer subsistence to delegates who had arrived the day prior to the meeting. The Panel noted that a buffet lunch was offered on the Sunday. The Panel queried whether the arrangements for the lunch on the Sunday were appropriate noting that it was served 30 minutes after the end of the meeting and cost €42.35 per person including alcohol. In the Panel's view, this was on the limits of acceptability.

The Panel noted Almirall's submission for the arrangements for the dinner on the Saturday evening. It was held in the venue mentioned by the complainant, however, Almirall submitted that the room had been laid out very differently and there was no music or cabaret dancers contrary to the photographs provided by the complainant. The company submitted that no entertainment was provided and that the photographs provided by the complainant were from another event at the venue on a different date. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that entertainment other than food and drink was provided.

The Panel considered that it was important for a company to be mindful of the impression created by its activities. Taking all the circumstances into account the Panel did not consider that the hospitality on the Friday, Saturday or Sunday was, on balance, unreasonable. The Panel ruled no breach of the Code.

The Panel noted its rulings and the lack of evidence. The complainant had not shown that high standards had not been maintained. The Panel ruled no breaches of the Code including no breach of Clause 2.

An anonymous, non-contactable ex-employee complained about the arrangements for a meeting, 'Psoriasis Management of Patients OverTime – PsoMOT', organised by Almirall Spain to which UK doctors were invited to attend. Almirall marketed two medicines for the treatment of moderate to severe plaque psoriasis – Skilarence (dimethyl fumarate) and Ilumetri (tildrakizumab).

COMPLAINT

The complainant alleged that Almirall UK invited UK doctors to attend the lavish meeting in Berlin on Friday, 26 October 2018. Almirall UK selected and invited UK doctors to attend, based on their prescribing of Almirall products.

The meeting was attended by Almirall UK representatives and on Friday, 26 October guests flew in for a lavish dinner. There was no educational content on that day as per the invite.

On Saturday, 27 October there was a number of promotional presentations on Almirall's product from various paid speakers as per the agenda. In the evening a second lavish dinner with a music band and cabaret dancers was held at a named venue.

On Sunday there were more presentations on the company's product and the meeting finished at noon. A three course sit down lunch was provided.

The complainant provided a copy of a letter to delegates setting out the final arrangements for the forthcoming meeting; he/she also provided a number of photographs from what appeared to be an evening venue.

When writing to Almirall, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 22.1 of the Code.

RESPONSE

Almirall explained that the 2018 PsoMOT ('Psoriasis Management of patients OverTime') meeting was organised, managed and fully funded by Almirall S.A (parent company of Almirall UK), based in Barcelona, Spain. Almirall S.A also fully funded the attendance of all the UK health professionals.

Almirall submitted that PsoMOT took place in Berlin, Germany, on 27 and 28 October 2018 and was a highly educational scientific event, where renowned dermatology experts from across Europe shared their expertise. The meeting aimed to provide an opportunity for health professionals to further enhance their knowledge and experience in the area of dermatology with the interest of improving patient outcomes.

The meeting was structured into plenary lectures followed by interactive parallel workshops so that delegates could choose part of their programme according to their educational preference and interact closely with experts, as appropriate. A copy of the agenda was provided.

One hundred and fifty-one health professionals from twelve European countries, including the UK (n=17), attended the meeting and thus it was not an event specifically aimed at UK health professionals. As it was an international meeting, it was hosted in Berlin (ie a central city hub). Six international experts spoke at the meeting; none of the speakers were from the UK. Almirall provided a table to show delegate and employee attendance by country.

UK health professionals were the fourth largest group behind Germany, Spain and Italy. Across all countries, 80 Almirall staff attended the meeting.

Details of the four Almirall staff attendees from the UK were provided. Their roles were to be UK points of contact for health professionals; additionally, some of those attending would benefit from the learning at the educational meeting.

Almirall stated that the company had corporate standard operating procedures (SOPs) in place to ensure baseline procedures across the organisation world-wide. The 'Prescription only medicines promotional compliance SOP' clearly outlined the arrangements for hospitality and events which was applicable to all Almirall employees. A copy was provided.

Almirall submitted that in addition to compliance with the corporate SOPs, before any global event/meeting arrangements were made, an event was planned and all the arrangements were reviewed and approved via the global event approval form (EAF) to ensure compliance with the EFPIA Code as well as the event originator market code (in this case the Spanish Code); and the host market code, where the event was held (in this case the German Code).

The approval form for the meeting in question was compiled by global in Almirall S.A, and reviewed and approved in Germany, and also reviewed by members of the global team of Almirall S.A, from the marketing, medical and compliance departments in Spain. A copy of the form was provided.

Finally, as the meeting was organised, managed and fully funded by the global team (Almirall S.A), including the attendance of all the UK delegates, the UK team did not need to certify the arrangements for the meeting.

As stated above, the meeting was organised, managed and fully funded by Almirall S.A. The role of Almirall UK was only to nominate appropriate delegates, who were contacted directly by global to complete registration and logistical arrangements.

To approve the meeting arrangements and facilitate the nomination process and ensure compliance with the Code, the UK marketing team compiled a comprehensive local meeting approval form and a UK sales team health professional nomination briefing. The briefing, as well as the meeting approval form were reviewed by the UK and subsequently certified. Copies of the UK certified approval form and salesforce briefing were provided together with an email to the salesforce.

The only information the representatives had was in the briefing. Any further questions from health professionals about the meeting or the agenda and content etc, were referred to the UK medical team. The reactive response for the medical team was provided.

The UK nominations briefing to the salesforce provided information on the invitation process and

clearly stated that the meeting would be suitable for consultant dermatologists, specialist registrars (final year of training), associate specialists and GPs with a special interest (working in secondary care). The health professionals had to be involved in the management of psoriasis patients, have a justifiable learning need that would be met by attending the meeting and be willing to apply this learning to benefit patients, or benefit the NHS and maintain patient care. The briefing further stated that where possible Almirall should not invite health professionals who it had supported to attend previous Almirall meetings (within the last year), unless they were absolutely the most suitable person to invite from the local healthcare. Once the nominations were received by Almirall UK, they were reviewed by employees marketing and medical.

Almirall strongly disagreed with the complainant's assertion that UK health professionals were selected based on their prescribing habits of Almirall medicines, this was clearly not the case.

Almirall UK selected the individual health professionals and the global team from Almirall S.A issued the invitations and funded the trip. The UK team helped draft some of the content of the invite to ensure a smooth transition of communication to the health professionals. The UK health professionals would initially have been told about the meeting by a representative but the official invite and meeting details would have been sent from Almirall S.A although the UK team also examined the final invitation email. Copies of relevant emails were provided.

Almirall S.A was sited in Spain. Under the Spanish Code, the expenditure on subsistence was a maximum cost per guest of €60 (including taxes) for any form of hospitality associated with meals and/or lunches. The threshold for subsistence was also €60 in Germany, and according to the UK Code the cost of a meal (including drinks) provided by way of subsistence must not exceed £75 (excluding VAT and gratuities) per person.

Almirall stated that all meals (lunches and dinners) provided during the PsoMOT meeting complied with the respective code(s). In addition, no entertainment was provided during the dinner on Saturday, 27 October or any of the lunch and/or dinners during the entire meeting. As the meeting was due to start at 08.15 on Saturday, 27 October, some delegates flew in the night before. Dinners in line with the Code(s) requirements were provided.

Due to the international nature of the meeting and the large delegate group flying in from different countries, at different times, dinners at separate locations were organised on Friday, 26 October. All the venues and subsistence thresholds were within the limits of Germany, the host country for the meeting.

10 delegates in total (UK health professionals and Almirall UK staff) attended the dinner from the UK on Friday night. Almirall provided details of the dinner menu and the final invoice for the meal.

Almirall UK stated that neither it nor global (Almirall S.A) knew of any issues with the meeting or its arrangements until the letter from the Authority in May 2019 (six months after the event). At that point the company became aware of the 'fake entertainment photos' and it was clearly very surprised and perplexed.

The UK and global team had diligently and transparently worked to provide the PMCPA with an accurate response. The matter had been investigated with full support and co-operation from relevant staff members locally as well as global colleagues, including senior management.

The photographs provided by the complainant, showing entertainment, appeared to be from the venue, where various types of events took place ranging from business events, group business dinners to personal events and social events etc. The venue could be 'dressed up' accordingly. Almirall submitted however that the complainant's photographs were not from the Almirall dinner. A basic Google search for images from the venue showed one of the alleged photographs as a thumbnail on the very first page. Clicking through this photograph led to a travel advice website where the other 'entertainment' photograph was available. Although a poor quality black and white photograph was submitted by the complainant, Almirall had found the original source and colour copies of two of the four photographs – which were freely available in the public domain. Almirall submitted that this without a doubt confirmed the false nature of the complaint and the claims made by the complainant.

A PsoMOT meeting dinner was hosted at the venue on Saturday, 29 October in order to cater for a large group (>240) of attendees. The venue was a private event, solely booked for the Almirall dinner on this date and the bar was closed during the dinner. The only subsistence provided was from the pre-agreed and approved arrangements. Copies of invoices were provided together with some photographs taken by a UK employee. The venue was an industrial looking events venue, with colourful fancy lighting. It had been used by many industries, including the pharmaceutical industry. It was selected as a venue that could easily accommodate a meal for >240 attendees.

Almirall emphasised that no entertainment was provided during the dinner on the Saturday or any of the lunches or dinners during the meeting. None of the lunches or dinners at PsoMOT were lavish and all complied with the respective code(s).

No additional hospitality was provided to the UK health professionals.

Scientific sessions were held on the Sunday morning from 09.00 to 11.30. There was no 3-course sit down lunch provided on Sunday, as alleged. Instead a buffet lunch was provided at the meeting venue, immediately after the sessions finished and before attendees' return flights in the afternoon, to ensure a proper meal before the long journeys (approximately 2-4 hours travelling time) to their countries of origin

for most of the delegates. The cost breakdown of each meal was provided which included information on the menu as well as the cost of food and beverage per person, which was €42.35 – all within the code(s) thresholds. For overall completeness Almirall provided a copy of the final invoice for the PsoMOT meeting.

Almirall stated that PsoMOT was a highly educational scientific meeting. The information covered was, objective, balanced and of scientific interest. Almirall provided information on the number of slides used in each session of the meeting and how many of those slides included the names of medicines and how many referred to Almirall's medicines (Skilarence and tildrakizumab). Almirall stated that although references were made to some of its products, these were not intended to be promotional *per se*. In line with the non-promotional style of the meeting and a focus on education and science, no product branding or brand colours were used. The overall branding was Almirall corporate.

In line with standard European medical education principles, the content of the slides was managed independently by the expert speakers. All the slides were reviewed by the global medical affairs team and final revisions with the speakers were undertaken on-site in Berlin on Friday, 26 October in a slide review meeting.

In addition, to support the strength of the highly education scientific meeting, the overall attendees' evaluation of the meeting, for those who responded was very high, with all the topics and speaker evaluations achieving more than 4 rating as a quality average (from an evaluation of 1 = very poor to 5 = very good). This was testament to the intent and purpose of the educational meeting. The speaker evaluation feedback summary was provided.

The feedback from seven different UK health professionals included comments such as:

- 'The meeting was excellent – very informative.'
- 'Many thanks, [employee name redacted] for organising such an informative and enjoyable event. Your programme was well balanced and really useful for a practicing dermatologist as myself.'
- 'Dear [employee name redacted], I wanted to thank you again for the great meeting organised and your personal support.'
- 'Thank you [employee name redacted], the meeting was very helpful and well organised.'
- 'Dear [employee name redacted] Thank you for all the organisation you had done for me to attend this meeting. It was a great meeting and was organised well.'
- 'Thank you very much. It was a really useful event. Thank you for everything.'
- 'Kindly keep me posted any further future meetings/events.'

In summary, Almirall stated that it took its commitment to, and compliance with, the Code very seriously, with this ethos applied to everything it did. The company noted that the meeting took place

in October 2018 and it had taken over six months for the anonymous ex-employee to falsely report the matter and ask the PMCPA to investigate this complaint as a matter of urgency. Almirall could not help but be suspicious about the motives behind the allegations, especially combined with the false photographs. Almirall denied all alleged breaches of the Code.

PANEL RULING

The Panel considered this case under the 2016 Code. It noted there were differences between that Code and the current Code, the 2019 Code, in relation to certification for meetings held outside the UK.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority stated that anonymous complaints would be accepted but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

It was an established principle under the Code that the UK company was responsible for acts and omissions of its overseas affiliates that came within the scope of the Code. If it were otherwise UK companies would be able to rely on such acts and omissions as a means of circumventing the Code.

Possible reasons for choosing Berlin as a suitable venue given in an internal memo were that Skilarence was approved in Germany and thus it would be compliant to hold a psoriasis related Almirall event there and that Berlin was a well-connected city at a European level. The Panel noted that the largest group of delegates was from Germany.

The Panel noted that there was no evidence that the UK invitees were chosen on the basis of their prescribing of Almirall products. The briefing to the representatives set out the criteria and the nominations were reviewed by the marketing manager and the senior medical advisor. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that the prescribing of Almirall products was the reason for inviting the health professionals. Thus, no breach of the Code was ruled.

The Panel noted that Clause 22.1 stated that hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. Clause 22.1 applied to scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The supplementary information to Clause 22.1 also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'Would you and your company be willing to have these arrangements generally known?'. The

impression that was created by the arrangements for any meeting must always be kept in mind. The supplementary information to Clause 22.2 stated that the maximum of £75 plus VAT and gratuities (or local equivalent) did not apply when a meeting was held outside the UK in a European country where the national association is a member of EFPIA and thus covered by EFPIA Codes. In such circumstances, the limits in the host country code would apply. The limit in the German Code was €60 per meal including VAT.

According to the agenda for the meeting as provided by Almirall, it started at 08.15 on Saturday, 27 October and finished at 16.30 with 30 minutes for a morning coffee break and 90 minutes for lunch. The agenda for Sunday, 28 October started at 09.00 where delegates could choose to attend two sessions of parallel workshops followed by 30 minutes conclusion and wrap up finishing the meeting at 11.30. There was no mention on the agenda of the dinners on the Friday and Saturday evenings, nor of the lunch on the Sunday. The meeting schedule provided by the complainant had more detail about the arrangements including those for the dinners on Friday and Saturday and the lunch on Sunday. There was an inconsistency in that the complainant's document stated that the meeting started at 08.30 whereas the company version stated the meeting started at 08.15.

The various groups had dinner by country at different restaurants on the Friday evening and all the delegates had dinner together on the Saturday evening, sitting in country groups.

The Panel noted that the cost of the meal on the Friday evening for UK delegates including drinks and taxes was €60 per head as was cost of the dinner on the Saturday evening.

There was no agenda, presentations nor educational content provided on the Friday as alleged. The Panel considered that it was not necessarily unacceptable

to offer subsistence to delegates who had arrived the day prior to the meeting. The Panel noted that a buffet lunch was offered on the Sunday. The Panel queried whether the arrangements for the lunch on the Sunday were appropriate noting that it was served 30 minutes after the end of the meeting and cost €42.35 per person including alcohol. In the Panel's view, this was on the limits of acceptability.

The Panel noted Almirall's submission for the arrangements for the dinner on the Saturday evening. It was held in the venue mentioned by the complainant, however, Almirall submitted that the room had been laid out very differently and there was no music or cabaret dancers contrary to the photographs provided by the complainant. The company submitted that no entertainment was provided and that the photographs provided by the complainant were taken at another event at the venue on a different date. The Panel did not consider that the complainant had provided evidence to demonstrate on the balance of probabilities that entertainment other than food and drink was provided.

The Panel considered that it was important for a company to be mindful of the impression created by its activities. Taking all the circumstances into account the Panel did not consider that the hospitality on the Friday, Saturday or Sunday was, on balance, unreasonable. The Panel ruled no breach of Clause 22.1.

The Panel noted its rulings and the lack of evidence. The complainant had not shown that high standards had not been maintained. The Panel ruled no breach of Clauses 9.1 and 2.

Complaint received

1 May 2019

Case completed

20 August 2019