

**CASE AUTH/3200/5/19**

## **DIRECTOR/MEDIA v NAPP**

### **Arrangements for a meeting**

**A BBC radio 4 programme broadcast in May 2019 and a subsequent article published on the BBC website entitled ‘Doctors used as “guinea pigs” in opioid painkiller promotion’ were critical of the activities of Napp Pharmaceuticals Limited.**

**The PMCPA Constitution and Procedure is such that public criticism of the industry is taken up by the Director and dealt with as a complaint under the Code. The article included criticism of a meeting sponsored by Napp and held in New York and was therefore treated as a complaint under the Code.**

**The article and radio programme referred to UK pain specialists staying in a smart hotel in New York, eating in upscale restaurants and attending Broadway shows, paid for by Napp Pharmaceuticals. No date was given for the meeting other than the early 2000s.**

**The article and radio programme also referred to some pharmaceutical companies monitoring prescribing rates of doctors who had attended paid for trips and deliberately targeting those ‘they thought they could influence’**

**The transcript of the radio programme referred, *inter alia*, to the views of a health professional who was a consultant in chronic pain on the use of opioids in chronic pain. The transcript also referred to certain publications, and whether clinical trials related to how medicines were used in real life and whether this misled doctors. Reference was made to Purdue Pharma in the US and a settlement in relation to OxyContin. The transcript referred to Purdue’s response that it did not exert undue influence over key opinion leaders with regard to medical education programmes which the company sponsored but did not control the content of. This was followed by a discussion about whether the same tactics were used in the UK.**

**The transcript of the radio programme stated that in early 2000 Napp, which according to the transcript was the UK company related to Purdue Pharma, flew groups of UK doctors specialising in pain to New York to meet key opinion leaders. Reference was made to a lovely hotel and the amount of down time to do things on your own. There was entertainment laid on and this included a Broadway show and eating in nice restaurants. There was a trip to the headquarters of Purdue Pharma. It was advertised as an educational package and the idea of meeting the international thought leaders was described as a great hook for the health professional.**

**The transcript also referred to an editorial in a 2007 British Pain Society newsletter referring to the conflict of interest this kind of hospitality created for doctors. The health professional who was a consultant in chronic pain referred to feeling duped that the trip was going to facilitate connections with people he/she would not otherwise meet when in**

fact he/she was 'just a guinea pig to promote prescribing of a class of drug'. The educational initiatives were said to be run by the marketing departments of pharmaceutical companies.

In follow up correspondence the health professional noted the headline themes of the published article and that the BBC was aware that he/she did not want to be portrayed in this way. The health professional thought that the overseas meeting in question occurred in spring 2002 and was one of a series where consultants in pain were taken to New York. The hotel was on 7<sup>th</sup> Avenue and had no leisure facilities or restaurant. Visits were made to several New York hospitals. The trip lasted five days. Dinner was provided and the end of course dinner was held at the top of the Rockefeller Centre. Attendees could go to a Broadway show. A helicopter trip round Manhattan was also provided.

The detailed response from Napp is given below.

The Panel noted that the meeting appeared to have taken place in 2002. The requirements of the 2001 Code therefore applied. The Panel noted that as with all such cases the complaint including any supporting evidence had to establish the case on the balance of probabilities although the evidence provided by both parties would be taken into account. In this regard, the Panel noted Napp's submission that its archive did not contain any original documentation in respect of certified materials and that relevant financial records were destroyed in 2013. Napp stated that it had to rely on the recollection of its one remaining employee who had some recollection of the programme. In this regard, the Panel noted that Napp was able to provide some details about the meeting. The health professional contacted by the Case Preparation Manager had also provided his/her recollection of the events in question. The Panel noted that it also had to bear in mind the Code standards and interpretation prevalent in 2002 in relation to meetings.

The Panel noted that the BBC article which formed part of the complaint referred to networking opportunities. One delegate named in the BBC article stated that the meeting was presented as an educational package, an opportunity to meet international thought leaders. The delegate now regretted attending stating that she/he was 'a guinea pig to promote the prescribing of a class of drug'. The delegate in subsequent correspondence with the PMCPA explained that the trip was one of a series. He/she had met opioid thought leaders at New York hospitals and visited the headquarters of Purdue Pharma. The delegate described a 'pleasant' but apparently modest hotel with no leisure facilities or restaurant. He/she also recalled dinner at the top of the Rockefeller Centre, an invitation to attend a Broadway show, and a helicopter ride around Manhattan, all provided as part of the trip.

The Panel noted that according to Napp it understood that around 15 delegates who were all pain specialists would have attended. It stated that the primary purpose of the meeting was educational, to foster an exchange of ideas and clinical practice between US and UK pain specialists. The reason for taking the UK health professionals outside the UK was to enable UK health professionals to attend US pain clinics and see practical demonstrations of the delivery of pain services.

The Panel noted its comments about the evidential issues that arose given the meeting happened in approximately 2002 both in terms of recollection of events and retention of

materials. Nonetheless, there was some common ground between the matters raised in the complaint and the account of the delegate and Napp's submission.

The Panel considered that based on the limited evidence before it there did appear to be an educational element to the meeting. The Panel also noted in this regard that the complaint had to establish the case on the balance of probabilities and there was insufficient evidence before the Panel to establish whether the content of the meeting met the requirement of having a clear educational content or not as set out in the Code and no breach of the Code was ruled on that narrow point.

The Panel noted that the impression created by the arrangements was important and that delegates should be attracted by an educational programme rather than the fact that the meeting was held over 5 days in New York. Whilst accepting that modern digital ways of holding such meetings were not generally available in 2002 the Panel did not consider that it would have been considered acceptable in 2002 to take approximately 15 health professionals to New York for 5 days for what appeared to the Panel, on the limited information available, to be a company promotional meeting. The Panel noted its ruling above of no breach of the Code in relation to the educational content. Napp's stated aim of fostering debate between UK and US based specialists and visiting local pain clinics did not, in the view of the Panel, of itself justify taking UK health professional outside of the UK for a 5 day stay in New York which might be viewed as an attractive tourist location and in this regard the Panel ruled a breach of the Code.

The Panel noted that whilst Napp stated that it was not aware of the helicopter tour mentioned by the delegate, in relation to the delegate's recollection that he/she had been invited to a Broadway show Napp understood that tickets may have been arranged for one show during the trip. The Panel decided that given the parties' similar evidence on this point, on the balance of probabilities, such tickets had been arranged. The Panel noted that hospitality must be secondary to the nature of the meeting and not out of proportion to the occasion. The Panel considered that in 2002 the provision of entertainment such as Broadway theatre tickets/trips would have been unacceptable under the requirements of the Code including the clause which prohibited the provision of gifts/ benefits in kind as an inducement. A breach of the Code was ruled.

High standards had not been maintained; a breach of the Code was ruled. The Panel noted its rulings above, particularly the impression given, and decided that in 2002, when the activities took place, they brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

An article entitled 'Doctors used as "guinea pigs" in opioid painkiller promotion' was published on the BBC website on 15 May following broadcast of File on 4, a BBC radio programme, on Tuesday, 14 May 2019. Both the radio programme and the website article were critical of the activities of Napp Pharmaceuticals Limited.

The PMCPA Constitution and Procedure is such that public criticism of the industry is taken up by the Director and dealt with as a complaint under the Code (Paragraph 6). The article included criticism of a meeting sponsored by Napp and held in New York. It was treated as a complaint under the Code.

Napp was also provided with a transcript of the radio programme and what was thought to be an article referred to and published in the British Pain Society Newsletter.

The journalist was asked by the Case Preparation Manager if he/she wanted to be involved in the case and whether she had additional information to submit as set out in Paragraph 6.1 of the Constitution and Procedure. The journalist stated verbally that he/she wanted to be involved. A health professional interviewed on the radio programme was also contacted by the Case Preparation Manager and provided additional information which was provided to Napp.

## COMPLAINT

The article and radio programme referred to UK pain specialists staying in a smart hotel in New York, eating in upscale restaurants and attending Broadway shows, paid for by Napp Pharmaceuticals. No date was given for the meeting other than the early 2000s.

The article and programme also refer to some pharmaceutical companies monitoring prescribing rates of doctors who had attended paid for trips and deliberately targeting those 'they thought they could influence'.

A transcript of the radio programme was published on the BBC website. The programme featured, *inter alia*, a consultant in chronic pain who was interviewed about his/her work in training GPs and that she used to work in high dose opioid clinics. The transcript referred to his/her views in relation to prescribing opioids for patients with chronic pain. Reference was made to publications in relation to opioid efficacy, and clinical trials and how they related to how medicines were used in real life and that this might have misled health professionals. The transcript stated that in America it had been established that doctors and patients were misled with catastrophic consequences. Reference was made to Purdue Pharma in the US and a settlement in relation to misbranding of its product OxyContin. The transcript referred to Purdue's response that it did not exert undue influence over key opinion leaders with regard to medical education programmes which the company sponsored but did not control the content of. This was followed by a discussion about whether the same tactics were used in the UK.

The transcript stated that in early 2000 Napp, which according to the transcript was the UK company related to Purdue Pharma, flew groups of UK doctors specialising in pain to New York to meet key opinion leaders. Reference was made to a lovely hotel and the amount of down time to do things on your own. There was entertainment laid on and this included a Broadway show and eating in nice restaurants. There was a trip to the headquarters of Purdue Pharma. It was advertised as an educational package and the idea of meeting the international thought leaders was described as a great hook for the health professional.

The presenter referred to an editorial in a 2007 British Pain Society newsletter referring to the conflict of interest this kind of hospitality created for doctors. The presenter also referred to the company monitoring prescribing habits before and after the trip and that the majority of health professionals started prescribing more of the product. The health professional referred to feeling duped that the trip was going to facilitate connections with people she would not otherwise meet when in fact she was 'just a guinea pig to promote prescribing of a class of drug'. The educational initiatives were said to be run by the marketing departments of pharmaceutical companies.

In correspondence with the Case Preparation Manager the health professional noted the headline themes of the published article and that the BBC was aware that he/she did not want to be portrayed in this way. The health professional thought that the overseas meeting in question occurred in spring 2002 and was one of a series where consultants in pain were taken to New York. The hotel was on 7<sup>th</sup> Avenue and had no leisure facilities or restaurant. Visits were made to several New York hospitals. The trip lasted five days. Dinner was provided and the end of course dinner was held at the top of the Rockefeller Centre. Attendees could go to a Broadway show. A helicopter trip round Manhattan was also provided.

When writing to Napp it was made clear that the date of the meeting was relevant in deciding which version of the Code applied. The radio programme referred to early 2000. It was thus likely that either the 1998 or the 2001 Code applied. The case would be considered under the 2019 Constitution and Procedure. Napp was asked to bear in mind the requirements of Clauses 2, 9.1, 18.1 and 19.1 of the 1998 Code. The relevant clauses in the 2001 Code were the same ie 2, 9.1, 18.1 and 19.1.

## **RESPONSE**

Napp submitted that the company archive did not contain any original documentation in respect of certified materials relating to this matter. Financial records in respect of the early 2000s appeared to have been destroyed in 2013. The final attendee list would have been included within the certified job bag. Napp understood that around 15 delegates would have attended with up to four Napp staff accompanying the group. Napp had no materials relating to the meeting which were sent to the delegates after the event and/or distributed in-house. To the extent that such materials were sent, they no longer existed. Napp noted the health professional's email to the Case Preparation Manager and his/her recollection of certain aspects of his/her visit. The company was unable to verify or add additional detail.

Napp submitted that it had no financial records relating to the visit. It noted that the health professional referred to the cost of certain meals being met privately by the attendees. Napp submitted that it was not aware of arranging the helicopter tour mentioned. Napp noted the health professional's recollection regarding tickets for a Broadway show and understood that tickets might have been arranged for one show during the trip.

Napp noted that the health professional made no reference to receiving any fee and did not believe any fees were paid.

Napp stated that it had no reason to doubt the health professional's recollection that the visit took place in 2002.

The health professional delegates were selected based upon each of them being pain specialist doctors in either palliative care (ie cancer pain), or non-cancer pain.

Napp submitted that the primary purpose of the meeting was educational, intended to provide an exchange of ideas and clinical best practice between UK and US (New York) pain specialists, fostering clinical debate and understanding about pain management. It believed that the reason for taking the UK health professionals outside of the UK to the US was to enable the UK health professionals to attend US specialist pain clinics and to see practical demonstrations of the delivery of pain services.

The company submitted that 6 such meetings were held.

Napp submitted that it did not believe it had ever been Napp's practice to monitor individual doctor prescribing. Moreover, Napp actually did not have the capacity to carry out such monitoring. In the UK prescribing information for all prescription medicines is purchased by Napp from a third-party provider that had confirmed that data for prescribing of individual doctors was not passed on to companies and could not have been captured by Napp from the third party. The third party provider was not aware of any other company that would be able to provide this level of individual health professional prescribing data. To Napp's knowledge the position, as outlined by the third party provider today, was no different to that prevailing in 2002, save that whatever information was available in 2002 was in hard copy form rather than electronic.

With regard to the PMCPA reference to the article ('Conflict of Interest – for discussion') written in the British Pain Society newsletter in 2007 which was referred to in the BBC File on 4 programme, Napp pointed out that the article in the newsletter did not name any company when it stated: '*took selected groups of pain doctors to New York to visit pain clinics*'. The article in question asserted that: '*the company monitored your prescribing habits before and after the trip*'. Irrespective of which company the newsletter article alluded to, individual monitoring of prescribing was not and could not be undertaken. In respect of an annual company conference where a '*jubilant marketing manager*' is said to have presented slides on '*increased profit*', Napp submitted that there were no actual facts which it could investigate or to which it could respond. Napp submitted that it believed that such behaviour was unlikely to have happened at Napp.

In relation to the health professional's email to the Case Preparation Manager Napp observed that it was faced with a complaint of considerable gravity built on two elements. The first was the reporting by the BBC whose approach to this story was in Napp's view deeply flawed in both content and tone. The health professional who was the main subject matter expert featured on the programme, now described him/herself as feeling '*very let down*' by the programme makers. The second was the newsletter article authored 12 years ago which merely alluded to certain anonymous events. Napp submitted that if the author of the newsletter article had confidence in the subject matter of his article, he/she was quite at liberty to name the company involved, yet he/she chose not to do so.

Napp submitted that it had endeavoured to respond to the substance of the complaint as best as the passage of some 17 years would allow. It had no access to relevant job bags or financial records and in consequence had to rely in large part on the memory of one remaining employee who had some recollection of the programme.

## **PANEL RULING**

The Panel noted that the meeting appeared to have taken place in 2002. The requirements of the 2001 Code therefore applied. The Panel noted that as with all such cases the complaint including any supporting evidence had to establish the case on the balance of probabilities although the evidence provided by both parties would be taken into account. In this regard, the Panel noted Napp's submission that its archive did not contain any original documentation in respect of certified materials and that relevant financial records were destroyed in 2013. Napp stated that it had to rely on the recollection of its one remaining employee who had some recollection of the programme. In this regard, the Panel noted that Napp was able to provide some details about the meeting. The health professional contacted by the Case Preparation

Manager had also provided his/her recollection of the events in question. The Panel noted that it also had to bear in mind the Code standards and interpretation prevalent in 2002 in relation to meetings.

The Panel noted that Clause 19.1 of the 2001 Code and its supplementary information stated that hospitality must be in association with an event and must be secondary to the purpose of that event. The level of hospitality offered must be appropriate and not out of proportion to the occasion. Clause 19.1 applied to scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The supplementary information 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 19.1 also stated that when company meetings involve health professionals at venues outside of the UK such meetings are not necessarily unacceptable but there must be valid and cogent reasons for holding meetings at such venues. As with any meeting it should be the programme that attracts delegates not the venue or associated hospitality.

The Panel noted that the BBC article which formed part of the complaint referred to networking opportunities. One delegate named in the BBC article stated that the meeting was presented as an educational package, an opportunity to meet international thought leaders. The delegate now regretted attending stating that she/he was 'a guinea pig to promote the prescribing of a class of drug'. The delegate in subsequent correspondence with the PMCPA explained that the trip was one of a series. He/she had met opioid thought leaders at New York hospitals and visited the headquarters of Purdue Pharma. The delegate described a 'pleasant' but apparently modest hotel with no leisure facilities or restaurant. He/she also recalled dinner at the top of the Rockefeller Centre, an invitation to attend a Broadway show, and a helicopter ride around Manhattan, all provided as part of the trip.

The Panel noted that according to Napp it understood that around 15 delegates who were all pain specialists would have attended. It stated that the primary purpose of the meeting was educational, to foster an exchange of ideas and clinical practice between US and UK pain specialists. The reason for taking the UK health professionals outside the UK was to enable UK health professionals to attend US pain clinics and see practical demonstrations of the delivery of pain services.

The Panel noted its comments about the evidential issues that arose given the meeting happened in approximately 2002 both in terms of recollection of events and retention of materials. Nonetheless, there was some common ground between the matters raised in the complaint and the account of the delegate and Napp's submission.

The Panel considered that based on the limited evidence before it there did appear to be an educational element to the meeting. The Panel also noted in this regard that the complaint had to establish the case on the balance of probabilities and there was insufficient evidence before the Panel to establish whether the content of the meeting met the requirement of having a clear educational content or not as set out in Clause 19.1. No breach of Clause 19.1 of the 2001 Code was ruled on that narrow point.

The Panel noted that the impression created by the arrangements was important and that delegates should be attracted by an educational programme rather than the fact that the meeting was held over 5 days in New York. Whilst accepting that modern digital ways of holding such meetings were not generally available in 2002 the Panel did not consider that it would have been considered acceptable in 2002 to take approximately 15 health professionals to New York for 5 days for what appeared to the Panel, on the limited information available, to be a company promotional meeting. The Panel noted its ruling above of no breach of Clause 19.1. Napp's stated aim of fostering debate between UK and US based specialists and visiting local pain clinics did not, in the view of the Panel, of itself justify taking UK health professional outside of the UK for a 5 day stay in New York which might be viewed as an attractive tourist location and in this regard the Panel ruled a breach of Clause 19.1.

The Panel noted that whilst Napp stated that it was not aware of the helicopter tour mentioned by the delegate, in relation to the delegate's recollection that he/she had been invited to a Broadway show Napp understood that tickets may have been arranged for one show during the trip. The Panel decided that given the parties' similar evidence on this point, on the balance of probabilities, such tickets had been arranged. The Panel noted that the supplementary information to Clause 19.1 stated that hospitality must be secondary to the nature of the meeting and not out of proportion to the occasion. The Panel considered that in 2002 the provision of entertainment such as Broadway theatre tickets/trips would have been unacceptable under the requirements of Clause 19.1 and Clause 18.1 which prohibited the provision of gifts/ benefits in kind as an inducement. A breach of Clauses 18.1 and 19.1 was ruled.

High standards had not been maintained; a breach of Clause 9.1 was ruled. The Panel noted its rulings above, particularly the impression given, and decided that in 2002, when the activities took place, they brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

[Post-hoc note: At the conclusion of this case Napp advised that it is a company independent of, but associated with, Purdue Pharma.]

**Complaint received**      **21 May 2019**

**Case completed**        **3 April 2020**