

# VOLUNTARY ADMISSION BY NAPP

## Conduct of representative

Napp Pharmaceuticals voluntarily admitted that one of its representatives had potentially gained an interview with a health professional under the false pretence of wanting to discuss a new medicine when he/she only wanted to discuss an existing one. Further, the representative had also appeared to link the health professional's opinion of Napp's medicines to the company's sponsorship of a conference.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

The detailed response from Napp is given below.

The Panel noted that according to Napp the consultant and representative each gave differing accounts of the basis upon which the representative had gained the interview. The consultant understood that the meeting was arranged to discuss a new product and had felt tricked into the appointment when the representative had explained that he could not discuss it. The consultant subsequently stated that he could not recall how the meeting had been arranged and acknowledged that his secretary might have misunderstood about the new product. The representative, however, consistently denied gaining an appointment under false pretence and maintained that he/she had always intended to, and had discussed, Targinact during the appointment. No new products were referred to. The representative's position in this regard was supported by an email from the representative apparently to the consultant's secretary and from the logging and record of the appointment in the company's internal systems. The Panel noted that the health professional had been sufficiently concerned to complain about the matter to his local health management which had subsequently contacted Napp. Nonetheless, in the Panel's view and on the available evidence, it was impossible to determine whether the interview with the consultant was gained under the false pretence of wanting to discuss a new medicine and the Panel therefore ruled no breach of the Code. Neither was there any evidence to suggest that the word 'new' had been used to describe a product. No breach of the Code was ruled. Consequently, the Panel did not consider that Napp had failed to maintain high standards and ruled no breach of the Code including Clause 2.

The Panel noted that the second admission concerned an apparent link between the consultant's and local health professionals' opinions of Napp's medicines and the company's sponsorship of a conference. The first aspect of this admission concerned what was said during

the meeting between the representative and the consultant and the second aspect concerned what was stated in emails to the conference organiser. In relation to the meeting, again the consultant and the representative gave differing accounts although both agreed that the conference had been discussed - the representative denied discussing cancellation or levels of sponsorship whilst the consultant stated that they had discussed the event in great detail. The consultant believed that the representative wished to cancel Napp's sponsorship because he did not have positive opinions about Targinact and because of what he had said about 'wider opinions' about the product; the consultant later recognised that he did not check his understanding with the representative at the time.

The Panel noted that in an email to the conference organiser, the representative stated that he/she had initially looked at becoming a gold sponsor and continued 'However, after a discussion with a senior palliative care clinician he informs me that our product does not have much relevance within palliative care in [named region]'. The representative indicated that he/she would still sponsor the meeting but at a lower level. This position was reiterated in a further email which concluded 'The meeting will be useful in getting the views of other clinicians around ... and hopefully if positive we can step up to gold sponsor next year'. The representative had subsequently advised Napp that he/she had reduced the level of sponsorship on receipt of an internal business email detailing new business needs and budgetary requirements. The Panel noted that there was no evidence that the consultant was copied in on the email to the conference organiser or otherwise provided with a copy of it. Nor was there any evidence to indicate that the complainant was the senior palliative care clinician referred to in the email. Nonetheless, the Panel noted that the email to the conference organiser was consistent with that consultant's view that conference sponsorship was linked to positive views on Targinact and its use. Similarly, the Panel noted that the email was consistent with the representative's position that the level of sponsorship was to be reduced rather than cancelled.

The Panel considered there was insufficient evidence to determine precisely what was said about sponsorship at the meeting between the consultant and the representative. Nor was there any evidence before the Panel that any personal benefit would accrue to the consultant as a result of such sponsorship. The Panel thus ruled no breaches of the Code including Clause 2.

In relation to the emails to the conference organiser, in the Panel's view these clearly implied that the

**company's provision of gold level sponsorship was dependent upon Napp's product (not named) being seen by a senior palliative care clinician to be relevant within the region. This was contrary to the Code and a breach was ruled. The representative had not maintained a high standard of ethical conduct in this regard and a breach of the Code was ruled. The Panel was very concerned about the unacceptable impression created by the emails; high standards had not been maintained and a breach of the Code was ruled. Nonetheless, it did not consider that the circumstances warranted a ruling of a breach of Clause 2 and no breach of that clause was ruled.**

Napp Pharmaceuticals Limited voluntarily admitted that one of its representatives had potentially gained an interview with a health professional under the false pretence of wanting to discuss a new medicine when he/she only wanted to discuss an existing medicine. Further, the representative had also appeared to link the health professional's opinion of Napp's medicines to the company's sponsorship of a meeting.

In accordance with Paragraph 5.5 of the Constitution and Procedure the admission was treated as a complaint and the matter was taken up with Napp.

## COMPLAINT

Napp explained that the representative in question had many years' experience and had latterly joined the company as an account manager for the specialist pain team which promoted Targinact (oxycodone/naloxone combination) tablets which received a marketing authorization in December 2008. The representative had passed the ABPI examination before joining Napp and as part of his/her induction to the company, received mandatory internal training on Targinact, Code of Business Ethics, systems training, and compliance in the field. In March 2014 someone telephoned on behalf of a hospital pharmacist and asked to speak to the representative's manager but gave no detail as to why. Upon notification of this request, the representative's manager returned the call but was informed that the person no longer wanted to discuss the matter on the telephone but instead would write an official letter directly to Napp. However, no letter was received and since the circumstances of the matter were not disclosed to Napp, following discussion between the representative's manager and personnel, no further action was taken at that time.

In April 2014, a clinical effectiveness pharmacist (from the same locality as the pharmacist referred to above) telephoned the representative's manager to discuss a complaint he had received from a palliative care consultant about the behaviour of the representative during a medical sales appointment between the consultant and the representative in March. During this telephone conversation the nature of the complaint, which was subsequently confirmed in an email, could be divided into two distinct elements.

Firstly, gaining an appointment with a health professional under false pretence. The allegation was that the appointment with the consultant was believed to have been made to discuss a 'new drug', but instead Targinact was discussed, viz. 'The consultant felt "tricked" into an appointment'. The second allegation concerned the withdrawal and possible cancellation of monetary sponsorship of a regional palliative care conference because of the consultant's negative view of Targinact – interpreted by the consultant and the local health managers to be the basis of an inducement to prescribe.

Given the serious nature of these allegations and potential breaches of the Code, as a result of this telephone conversation, the representative's manager immediately arranged an investigatory meeting with the representative.

The representative denied the first allegation and showed an email trail which detailed how the initial appointment with the consultant was arranged and booked and in which the representative verified and made it clear that there was no mention of 'discussion of a new product' or any similar words in arranging for and booking the meeting. The representative also made it clear that in the logging and record of the completed appointment on internal company systems there was no mention of 'new product' or the word 'new' and also that this was the case in the telephone call to the consultant's secretary.

The representative confirmed that he/she discussed the palliative care conference with the consultant but denied discussing the cancellation or reduction in monetary sponsorship for the conference. This was contrary to the consultant's and the health manager's view. The representative also understood that both the consultant and the health manager were of the view that sponsorship of the conference had been completely withdrawn. The representative noted that monetary sponsorship had only been reduced, not cancelled. The representative explained that he/she had decided to reduce the level of sponsorship in response to recent information sent to him/her about business needs and budgetary requirements.

Napp telephoned the consultant, who stated that he could not remember how the meeting had been arranged and his secretary could have possibly misunderstood about the new product. The consultant noted that the representative stated that he/she could not talk about the new product even though the consultant had asked about it and he/she wanted to speak about Targinact.

However, the consultant was clear that, viz. '... [we] spoke about the sponsored event. [The representative] stated that he/she had intended to sponsor the event but given what [the consultant] had said about 'wider opinion' [the representative] now probably wouldn't'. The consultant stated that he believed the representative wanted to cancel sponsorship for the conference because the consultant did not have positive opinions about Targinact, although the consultant also

recognised and stated that ‘... [I] did not check [my] understanding with [the representative] at the time.’ Napp informed the consultant that the representative had acknowledged discussing the conference with him, but he/she denied discussing sponsorship or levels of sponsorship. The consultant refuted this position and replied that ‘[the representative] brought [the discussion of the event] up and they had discussed the event in great detail’.

Following this telephone call with the consultant, Napp considered that it needed to speak to the representative again and at a second meeting the representative verified and confirmed the statements he/she had made in the first meeting. The representative also confirmed that during the appointment he/she only talked about Targinact and nothing ‘new’.

The representative again confirmed that he/she discussed the palliative care conference with the consultant but did not discuss cancelling or reducing, sponsorship; he/she had reduced the level of sponsorship for the conference based on the new information provided to him/her about business needs and budgetary requirements, not on the opinions of the consultant. The representative stated in an email to a conference organiser, ‘However, after a discussion with a senior palliative care clinician he informs me our product does not have much relevance within palliative care in [named region]’; the representative acknowledged that this might be interpreted incorrectly as an inducement to prescribe, but the representative detailed that no specific health professional (ie the consultant), nor any specific product (ie Targinact), was mentioned. The email trail also later contained the sentence ‘This meeting will be useful in getting the views of other clinicians ... and hopefully if positive we can step up to gold sponsor next year’.

As detailed in the email conversation between the clinical effectiveness pharmacist and the representative’s manager, a medicines management group (MMG) meeting was convened in May 2014. In consideration of this case with the available evidence to it, the MMG barred the representative with immediate effect, and also notified Napp that it would complain to the Authority with specific regard to the two allegations above. On notification of this decision, Napp subsequently informed the Authority accordingly.

Napp noted that the representative had recently left the company and so it had not been able to ask him/her further investigatory and confirmatory questions. Consequently, the true meaning and explanation of the ‘if positive’ wording in his/her email was unclear, and whether this was, or was not, intended as a true inducement to prescribe. Napp was unclear whether the ‘if positive’ statement referred specifically to the prescribing and use of Targinact, or whether it referred more broadly to the general view of clinicians on the palliative care conference itself.

As a consequence of this incomplete evidence, Napp reviewed and interpreted this case on the balance of probability and available evidence.

Napp provided a summary of the allegations as follows:

**Allegation 1:**

Gaining an appointment with a health professional under false pretence, *viz.* the meeting with the consultant alleged to have been gained and arranged to discuss a ‘new product’, but an old medicine (ie Targinact) was discussed instead.

**Clause 7.11**

Targinact is not a ‘new’ medicine. In the meeting between the consultant and the representative, Targinact was discussed. The representative’s account of the intention, arrangement and booking of the appointment with the consultant was not to discuss any ‘new’ medicine – it was always to discuss Targinact.

The evidence from email trails detailing the booking of the appointment and the representative’s and the consultant’s witness statements, did not indicate that it was ever the representative’s intention to discuss any ‘new product’ or anything ‘new’. Moreover, the consultant had stated and confirmed that the representative actually refused to talk about any new product or anything new at all, even despite direct questioning by the consultant. The consultant acknowledged that he could not fully remember how the meeting had been arranged and further affirmed that his secretary could have misunderstood that the meeting was arranged with the intention to talk about a ‘new product’. There was no record of any telephone calls which might have taken place between the secretary and the representative.

On the balance of the available evidence, Napp concluded that the representative did not use the word ‘new’ in arranging the appointment and thus Napp denied a breach of Clause 7.11.

**Clause 15.3**

Although the consultant had stated and believed that the appointment was gained under false pretence or subterfuge, as detailed above concerning Clause 7.11, there was no strong or confirmatory evidence to demonstrate that the appointment was gained with an intention to discuss a ‘new product’ or anything ‘new’. The consultant had stated that he could not himself be sure of the arrangements on how the appointment was made.

Napp thus denied a breach of Clause 15.3.

**Allegation 2:**

The monetary sponsorship of a conference made on the basis, and due to a health professional’s view, on a medicine interpreted as an inducement to prescribe, *viz.* the level of monetary sponsorship for the palliative care conference was reduced based on the consultant’s negative view on Targinact.

**Clause 15.2**

The representative’s emails were ambiguous and did not appear to uphold the high standards required by the Code.

Napp thus considered that there might have been a breach of Clause 15.2.

### **Clause 18.6**

There were conflicting views in the statements made by the representative, the consultant and the local health managers about the reasons for reducing monetary sponsorship of the conference or whether this was even discussed during the meeting, although it was certainly discussed by email, albeit with a conference organiser.

It was also clear that there were different possible interpretations relating to the temporality of the representative's decision to reduce sponsorship as detailed in his/her email to the conference organiser. The representative requested to reduce sponsorship after his/her appointment with the consultant, but did so also after an internal business email detailing the new business needs and budgetary requirements.

Finally, it was also clear that the precision and meaning of the representative's email sentences were unknown,

'... However, after a discussion with a senior palliative care clinician he informs me our product does not have much relevance within palliative care in [named region] ...' and,

'... This meeting will be useful in getting the views of other clinicians ... and hopefully if positive we can step up to gold sponsor next year ...'.

Napp stated that it was important to note that in these sentences, no health professional, ie the consultant, was specifically mentioned, that no product, ie Targinact, was specifically mentioned (indeed Napp marketed a wide range of varied products in different therapy areas that were used in palliative care), and to carefully consider whether the 'if positive' wording related specifically to a medicine (medicines), or more broadly on the health professional's views in general on the meeting itself.

Napp was thus unsure whether Clause 18.6 had been breached.

The Authority asked Napp to consider this matter in relation to Clauses 2, 7.11, 9.1, 15.2, 15.3, 18.1 and 18.6 of the Code.

### **RESPONSE**

In relation to Clause 9.1, Napp submitted, on the balance of its internal investigation, that the appointment with the consultant was not gained under a false pretence as alleged. The representative confirmed that he/she had reduced his/her contribution due to budgetary changes and a need to prioritise his/her spend. However, in relation to the second allegation, the wording in the emails might be considered ambiguous. Therefore, the Authority's opinion was sought on whether the representative had failed to uphold high standards.

In relation to Clause 18.1, Napp noted that the second allegation related to the provision of

sponsorship for the organisation of a health professional educational conference and not to a specific member (or members) of the health profession(s) including administrative staff. Napp submitted that this monetary sponsorship constituted a provision of medical educational goods and services to an institution and should therefore be considered under Clause 18.6 alone. Allegation 2 did not involve any specific gift, pecuniary advantage or benefit directly to the health professional(s) (ie the consultant or the local health managers) or to the organiser of the palliative care conference and therefore Napp did not believe that Clause 18.1 was applicable. However, if the Panel considered that Clause 18.1 was relevant, then Napp referred to its comments above regarding Clause 18.6 as the same rationale would apply to Clause 18.1. Napp denied a breach of Clause 18.1.

In relation to Clause 2, Napp did not believe from the evidence presented that the representative's conduct had brought discredit upon, or reduced confidence in, the pharmaceutical industry. Napp considered that there was sufficient uncertainty from the available hard evidence and investigation as to whether there had been clear breaches of Clauses 7.11, 9.1, 15.2, 15.3, 18.1 and 18.6 of the Code. Napp also considered it improbable that an ABPI qualified representative with many years' experience, who had been specifically trained on the Code and compliance when he/she joined Napp, would intentionally offer an inducement to prescribe. Napp believed it more likely that the unfortunate wording and turn of phrase in his/her emails was unintentional.

### **PANEL RULING**

The Panel noted that Napp's admission concerned the basis upon which one of its representatives had gained an interview with a consultant and an apparent link made by the representative at the interview and subsequently in an email to a meeting organiser, between Napp's sponsorship of a meeting and the consultant's opinion of its medicines. Neither the consultant nor the meeting organiser were party to the complaint.

According to Napp the consultant and representative each gave differing accounts of the basis upon which the representative had gained the interview. It was difficult in such circumstances to determine where the truth lay. A judgement had to be made on the available evidence. The consultant understood that the meeting was arranged to discuss a new product and advised Napp that he had felt tricked into the appointment when the representative had explained that he could not discuss it. According to Napp, the consultant had subsequently stated that he could not recall how the meeting had been arranged and acknowledged that his secretary could have possibly misunderstood about the new product. The representative, however, had consistently denied gaining an appointment under false pretence and maintained that he/she had always intended to, and had discussed, Targinact during the appointment. No new products were referred to. The Panel noted that a redacted email from the representative

apparently to the consultant's secretary referred to 'a pain product that I would like to discuss with you'. The product was not identified nor was it described as new. According to Napp, the representative's account was supported by the logging and record of the appointment in the company's internal systems. The Panel noted that the health professional had been sufficiently concerned to complain about the matter to his local health management which had subsequently contacted Napp. Nonetheless, in the Panel's view and on the available evidence, it was impossible to determine where the truth lay. There was insufficient evidence to establish whether the interview with the consultant was gained under the false pretence of wanting to discuss a new medicine and the Panel therefore ruled no breach of Clause 15.3. Neither was there any evidence to suggest that the word 'new' had been used to describe a product. No breach of Clause 7.11 was ruled. Consequently, the Panel ruled no breach of Clauses 9.1 and 2.

The Panel noted that the second admission concerned an apparent link between the consultant's and local health professionals' opinions of Napp's medicines and the company's sponsorship of a conference. The first aspect of this admission concerned what was said during the meeting between the representative and the consultant and the second aspect concerned what was stated in emails to the conference organiser. In relation to the meeting, again the consultant and the representative gave differing accounts although both agreed that the conference had been discussed. According to Napp, although the representative denied discussing cancellation or levels of sponsorship, the consultant refuted this and stated that they had discussed the event in great detail. The consultant believed that the representative wished to cancel Napp's sponsorship because he did not have positive opinions about Targinact and because of what he had said about 'wider opinions' about the product. According to Napp the consultant recognised that he did not check his understanding with the representative at the time. The Panel noted that the account of the consultant and the representative differed and noted its comments above about the difficulty of determining where the truth lay in such circumstances.

The Panel noted that in an email to the conference organiser, the representative stated that he/she had initially looked at becoming a gold sponsor and continued 'However, after a discussion with a senior palliative care clinician he informs me that our product does not have much relevance within palliative care in [named region]'. The representative explained that he/she was still willing to sponsor

the meeting and enquired about lower levels of sponsorship. This position was reiterated in another email which concluded 'The meeting will be useful in getting the views of other clinicians ... and hopefully if positive we can step up to gold sponsor next year'. The representative had subsequently advised Napp that he/she had reduced the level of sponsorship on receipt of an internal business email detailing new business needs and budgetary requirements. The Panel noted that there was no evidence that the consultant with whom the representative had held the initial meeting described above was copied in on the email to the conference organiser or otherwise provided with a copy of it. Nor was there any evidence to indicate that he was the senior palliative care clinician referred to in the email. Nonetheless, the Panel noted that the email to the conference organiser was consistent with that consultant's view that during the aforementioned meeting, sponsorship was linked to positive views on Targinact and its use. Similarly, the Panel noted that the email was consistent with the representative's position that the level of sponsorship was to be reduced rather than cancelled.

The Panel considered there was insufficient evidence to determine precisely what was said about sponsorship at the meeting between the consultant and the representative. Nor was there any evidence before the Panel that any personal benefit would accrue to the consultant as a result of such sponsorship. The Panel thus ruled no breach of Clause 18.1 and consequently Clauses 9.1 and 2.

In relation to the emails to the conference organiser, in the Panel's view these clearly implied that the company's provision of gold level sponsorship was dependent upon Napp's product (not named) being seen by a senior palliative care clinician to have relevance within the region. This was contrary to Clause 18.6 and a breach of that clause was ruled. The representative had not maintained a high standard of ethical conduct in this regard and a breach of Clause 15.2 was ruled. The Panel was very concerned about the unacceptable impression created by the emails; a breach of Clause 9.1 was ruled. Nonetheless, it did not consider that the circumstances warranted a ruling of a breach of Clause 2 which indicated particular censure and was reserved for such use. No breach of Clause 2 was ruled.

**Complaint received**                      **2 May 2014**

**Case completed**                              **8 July 2014**