VOLUNTARY ADMISSION BY NAPP

Provision of business class travel

Napp Pharmaceuticals voluntarily admitted that it had provided business class air travel to delegates attending a congress and that the arrangements had not been certified.

The Authority's Constitution and Procedure provided that the Director should treat an admission as a complaint if it related to a potentially serious breach of the Code. The Director considered that the matters disclosed were potentially serious and the admission was accordingly treated as a complaint.

Napp stated that it had supported 17 health professionals to attend an international congress in Montreal. Napp's congress team had tried to reserve premium economy seats as stipulated in the company's standard operating procedure (SOP) but as none were available, business class seats were reserved. Approval to book these seats was sought from Napp's legal department. In doing so, the meetings department wrongly referred to an SOP which permitted business class flights when travel for delegates was over 4 hours. In fact the SOP stated that 'economy plus' was acceptable for flights exceeding 4 hours. Business class was permitted for health professionals who were providing consultancy services. Approval to book the flights was granted, with the legal team being left with the impression that the flights were for consultants. Unfortunately the reservation of business class travel was not submitted for final certification. This unfortunate outcome was the result of a breakdown in internal communication and not a wilful attempt to flout the Code.

The fact that business class flights had erroneously been booked was only recognised three days before departure. In response to this, Napp's congress team tried to re-arrange the flights but despite checking with a number of airlines, direct premium economy and economy flights from London to Montreal were fully booked. Indirect flights were also checked, but the number of changes involved would have hugely disrupted the delegates' travel plans and their attendance for the duration of the congress. Napp therefore concluded that it would have damaged its reputation, and potentially that of the industry, more to require its delegates to change their travel plans on the outward bound journey at this very late stage.

All return flights, however, were rearranged and delegates were allocated economy seats on indirect flights back to London. Delegates were informed of the mistake in a letter (provided), which also advised them that their return journey had been changed. The revised travel arrangements,

however, were not acceptable to 16 of the 17 delegates who had various clinical or travel commitments to fulfil on their return to the UK. These delegates thus returned business class as previously arranged.

Napp took compliance very seriously; this was a genuine oversight and Napp had tried to rectify the situation being mindful of the need to minimise the inconvenience to the health professionals concerned. In addition, the process for the certification for international meeting arrangements was being reviewed to ensure that this mistake did not occur in the future. Extra bespoke training on the Code as it related to delegates, consultants and meeting arrangements would be provided to the congress team.

However, Napp appreciated that the circumstances described above potentially breached the Code in relation to the provision of business class flights to delegates attending an educational meeting and the failure to certify the final travel arrangements.

The detailed response from Napp is given below.

The Panel noted that the Code stated that companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Napp had provided business class travel to delegates sponsored to attend an international meeting in Canada. The Panel further noted that Napp had admitted that the delegates' final travel arrangements had not been certified. Breaches of the Code were ruled.

The Panel noted that potential delegates had not been offered sponsorship to include business class flights to Montreal and that at the outset the congress department had tried to book premium economy seats. As these were unavailable the congress department had sought approval from legal to book business class seats and misquoted the relevant SOP which clearly stated that economy fares (or economy plus fares for flights of longer than four hours) should be booked. Unfortunately the congress department's error in requesting the upgrade was further compounded by the legal department which granted approval on the mistaken basis that those travelling were consultants to the company. The Panel did not have details of the interaction between the two departments but noted that it appeared to have been conducted by email and in that regard the Panel queried how detailed the discussion had been. The congress team proceeded to book the business class flights and assumed that given the involvement of legal department, it did not need to

get the travel arrangements otherwise formally certified.

The Panel noted that the first the delegates would have known about the business class flights was in a letter dated 4 weeks before departure. The delegates were thus not attracted to the meeting on the basis of the class of air travel to be provided. It was, however, unacceptable that given the unavailability of the intended tickets, Napp's internal communications, processes and procedures had subsequently failed. The Panel considered that, notwithstanding the availability of tickets, the requirements of the Code should have been well known to the congress department. In that regard the Panel considered that Napp had been badly let down by its staff. However, the Panel noted Napp's submission that the relevant SOP at the time was not sufficiently clear about the need to certify arrangements for international meetings. This was unacceptable and might have been one of the factors which led to the congress department's mistake not being picked up. The Panel considered that overall high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that following the incident, Napp had rewritten one of the SOPs, to ensure that the need to certify arrangements relating to delegates' attendance at overseas meetings was clear, and had also arranged bespoke training for the congress department.

The Panel noted its comments above and further noted that Napp had given each delegate a letter which stated that the outbound travel arrangements did not comply with the Code. Delegates were further informed that the inbound flights would have to be changed. The Panel noted that the delegates flew home as previously arranged due to clinical/travel arrangements on their return. The Panel considered that the failure of Napp's policies and procedures demonstrated a lack of control in relation to the certification of all of the arrangements for overseas meetings and a lack of awareness of the relevant requirements of the Code. It was of concern that the relevant SOPs were not clear on this matter. The Panel considered that the incident was wholly unacceptable and brought discredit upon or reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case the Panel noted Napp's reference to premium economy tickets. The Code specifically referred only to the provision of economy air travel. There had never been any ruling under Code regarding the acceptability or otherwise of premium economy air travel. The Code of Practice Appeal Board would make the final decision in that regard if ever a complaint was made and taken to appeal.

Napp Pharmaceuticals Limited voluntarily admitted that it had provided business class air travel to

delegates attending a congress in breach of Clause 19.1 of the Code and that the arrangements had not been certified as required by Clause 14.2.

Paragraph 5.4 of the Authority's Constitution and Procedure provided that the Director should treat an admission as a complaint if it related to a potentially serious breach of the Code. The Director considered that the matters disclosed were potentially serious and the admission was accordingly treated as a complaint.

COMPLAINT

Napp stated that it had supported 17 health professionals to attend the 13th World Congress on Pain being held in Montreal from 29 August to 2 September 2010 as delegates. The internal congress department was responsible for booking the delegates' flights and had tried to reserve premium economy seats between London and Montreal, as stipulated in Napp's standard operating procedure (SOP). Unfortunately none were available and so business class seats were reserved. Approval to book these seats was sought from Napp's legal department. In doing so, the meetings department wrongly referred to an SOP which permitted business class flights when travel for delegates was over 4 hours. In fact the SOP stated that 'economy plus' was acceptable for flights exceeding 4 hours. Business class was permitted for health professionals who were providing consultancy services. Approval to book the flights was granted, with the legal team being left with the impression that the flights were for consultants. Unfortunately the details of this change of arrangements were not submitted for final certification. Therefore business class air travel was booked for the delegates and these specific arrangements were not formally certified. This unfortunate outcome was the result of a breakdown in internal communication and was not a wilful attempt to flout the Code.

The fact that business class flights had erroneously been booked was only recognised three days before the departure date. In response to this, Napp's congress team tried to re-arrange the flights to ensure compliance with the Code, specifically Clause 19.1. However, unfortunately at this late stage, despite checking with a number of airlines, direct premium economy and economy flights from London to Montreal were fully booked. Indirect flights were also checked, but the number of changes involved would have hugely disrupted the delegates' travel plans and their attendance for the duration of the congress. Napp therefore concluded that it would have damaged its reputation, and potentially that of the industry, more to require its delegates to change their travel plans on the outward bound journey at this very late stage.

All return flights, however, were rearranged and all delegates were allocated economy seats on return flights from Montreal to London either via Toronto or Halifax. Delegates were informed of the mistake in a letter (provided), which also advised them that their travel arrangements for the return journey had been changed.

Because of the change in arrival times to the UK, and the fact that at least five of the delegates had to attend clinics on the day they returned to the UK, Napp agreed to continue to try to book direct return premium economy flights while the congress was ongoing, but, should this prove impossible, Napp had agreed that business class flights would be provided to those individuals.

Napp took compliance with the Code very seriously. This was a genuine oversight and Napp had tried to rectify the situation being mindful of the need to minimise the inconvenience to the health professionals concerned. In addition, the internal process for the certification for international meeting arrangements was being reviewed to ensure that this mistake did not occur in the future. Extra bespoke training on the Code as it related to delegates, consultants and meeting arrangements would be provided to the congress team responsible for booking travel arrangements for sponsored delegates.

However, Napp appreciated that the circumstances described above had led to two potential breaches of the Code; Clause 19.1 in relation to the provision of business class flights to delegates attending an educational meeting and Clause 14.2 with regard to the failure to certify the final travel arrangements.

When writing to Napp, the Authority asked it to respond in relation to Clauses 2, 9.1, 14.2 and 19.1.

RESPONSE

Napp reiterated that it had supported 17 health professionals to attend the 13th World Congress on Pain in Montreal from 29 August to 2 September 2010 as delegates. The sponsored delegates were erroneously provided with business class flights and the final travel arrangements for attendance at this international educational meeting were not formally certified. This unfortunate outcome was the result of an internal misunderstanding that the planned arrangements related to health professionals acting as consultants to the company, not delegates to a meeting, and of a failure to recognise that approval by Napp's legal department did not preclude the need for final certification.

With this background in mind, Napp commented specifically with regard to the requirements of Clauses 19.1, 14.2, 2 and 9.1 of the Code.

Clause 19.1: Providing business class air travel to delegates attending an international meeting

The Code stated that companies should only offer or provide economy class air travel to delegates sponsored to attend meetings. Napp recognised that it had inadvertently provided delegates

attending an educational meeting with business class air travel.

Clause 14.2: Failure to gain formal certification for the arrangements for an international meeting

The Code stated that all meetings which involved travel outside the UK must be certified in advance. On this occasion, the final arrangements for air travel for the delegates were not certified in advance of the meeting. Review of the SOPs relating to 'UK and overseas 3rd party organised meetings and congresses' (SAM-PRO-005 version 2) and the 'Provision of sponsorship for healthcare professionals to attend training or educational meetings' (SAM-PRO-009 version 2) which were in effect when the flights were booked, revealed that the stipulation for certification for international meeting arrangements was not sufficiently explicit. Therefore, the process relating to the organisation of Napp presence at UK and international congresses had since been reviewed, and the SOP had been completely re-written and simplified to ensure that the process, including the need for certification of arrangements relating to delegate attendance, was clear (SAM-PRO-005 version 3).

In addition, the medical department would train the congress team on the Code as it related to delegates, consultants and meeting arrangements on 24 September. Training on the new SOP would be provided at the same time.

Clause 2: Bringing discredit to, and reducing confidence in the industry

Whilst Napp appreciated that it had breached the Code as outlined above, it emphasised that every effort had been made to ensure that this unfortunate situation was handled in a responsible manner. Once the mistake was identified, attempts were immediately made to source alternative outbound flights. However, making such alternative arrangements at short notice would have disrupted the delegates' travel plans as they would have arrived late and potentially missed the beginning of the congress. Napp concluded that it could have damaged the industry's reputation more if it had required its delegates to change their outbound journey arrangements at this very late stage when the error was not their fault. Napp therefore decided to allow the delegates to travel business class on the outbound journey as planned, and told the Authority about the situation.

With respect to the return journey, Napp's congress team had reserved economy seats for all delegates. However, since those flights involved changing in either Toronto or Halifax and a different arrival time into the UK, during the course of the congress 16 delegates asked to return on the business class flight as originally booked. In Napp's view, all gave valid reasons for the need to be adequately rested following an overnight flight since they had work or travel commitments on the day of arrival. Details were provided. In the circumstances Napp decided

that the only responsible course of action was to allow them to fly business class as arranged. The remaining delegate extended his stay in Montreal post-congress, and a premium economy flight was arranged for his return.

With this in mind, rather than discrediting and reducing confidence in the industry, Napp believed the opposite was true, given the open and honest manner in which this genuine mistake was communicated and managed with the delegates. The Napp personnel involved behaved professionally and responsibly, ensuring that the delegates were not unnecessarily inconvenienced. In addition, on realising the mistake, Napp told the Authority of the potential breaches by way of a voluntary admission. Therefore Napp strongly refuted the claim that by providing business class travel as described above, that it had discredited or reduced confidence in the industry.

Clause 9.1: Failure to maintain high standards at all times

It was extremely unfortunate that this mistake occurred in the organisation of the flight arrangements, and as previously explained this was due to a genuine misunderstanding of information contained within email correspondence and an assumption that the planned arrangements related to consultants working for the company, not delegates to a meeting. It also highlighted a failure to recognise that approval by Napp's legal department did not preclude the need for final certification.

However, Napp strongly believed that the high standards demanded of the industry were demonstrated by the behaviour of its personnel in responding to the circumstances in a manner that ensured the least disruption to the delegates and their participation in the international congress. Furthermore, to avoid any similar incidents in the future, the company had provided the necessary training and ensured that the relevant processes were clearer.

In summary, Napp recognised that by providing business class flights to delegates attending an international educational meeting and failing to certify the final travel arrangements, breaches of Clauses 19.1 and 14.2 had occurred. However, for the reasons outlined above, Napp did not consider that its actions had brought discredit to or reduced confidence in the industry, nor did it believe that high standards had not been maintained. Therefore Napp denied breaches of Clauses 2 and 9.1.

In response to a request for further information, Napp provided a copy of the registration form. This form was completed by the health professional to confirm their interest in attending the meeting, following a verbal invitation from a sales representative. Napp noted that the briefing to the sales team from the congress team with respect to inviting individual health professionals did not

specify the class of air travel to be provided to the delegates, and indeed stated 'on receipt of the completed delegate details form I will contact the delegate to confirm their places and arrange appropriate travel etc'. Delegates were emailed with personalised outline information to confirm their attendance, accommodation and air travel arrangements, including connecting flights. The class of air travel to be provided was not stated in this email.

The confirmation letter sent to individual delegates, dated 30 July, confirmed the nature of the sponsorship to be provided. Flight confirmation was also provided with this letter, and was the first time that the majority of delegates (except for one, as outlined below) were told that Napp had booked business class flights.

In summary, the majority of delegates did not know that they would be flying business class until final travel arrangements were confirmed in the letter of 30 July. One exception to this was a delegate who contacted the Napp congress team to specifically ask '... what ticket are we flying with – economy/premium economy/business? It's just that I have a few airmiles which I could use to upgrade if possible'. The response from the congress team confirmed that business class air travel would be provided.

PANEL RULING

The Panel noted that the supplementary information to Clause 19.1 of the Code, Meetings and Hospitality, stated that companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Napp had provided business class travel to delegates sponsored to attend an international meeting in Canada. A breach of Clause 19.1 was ruled.

The Panel further noted that Clause 14.2 of the Code stated that all meetings which involved travel outside the UK must be certified in advance in a manner similar to that provided for by Clause 14.1. The relevant supplementary information stated that the signatories should examine, *inter alia*, the nature of the hospitality and the like. The Panel noted that Napp had voluntarily admitted that the delegates' final travel arrangements had not been certified. A breach of Clause 14.2 was ruled.

The Panel noted that potential delegates had not been offered sponsorship to include business class flights to Montreal. The registration form did not identify the class of air travel. At the outset the congress department had tried to book premium economy seats. As these were unavailable the congress department had sought approval from legal to book business class seats and misquoted the relevant SOP which clearly stated that economy fares (or economy plus fares for flights of longer than four hours) should be booked. Unfortunately the congress department's error in requesting the upgrade was further compounded by the legal

department which granted approval on the mistaken basis that those travelling were consultants to the company. The Panel did not have details of the interaction between the two departments but noted that it appeared to have been conducted by email and in that regard the Panel queried how detailed the discussion had been. The congress team proceeded to book the business class flights and assumed that given the involvement of legal department, it did not need to get the travel arrangements otherwise formally certified. In that regard the Panel noted Napp's submission that at the time the relevant SOP was not sufficiently clear about the need to certify arrangements for international meetings.

The Panel noted that the first the delegates would have known about the business class flights was in a letter dated 30 July (4 weeks before departure). The delegates were thus not attracted to the meeting on the basis of the class of air travel to be provided. It was, however, unacceptable that given the unavailability of the intended tickets, Napp's internal communications, processes and procedures had subsequently failed. The Panel considered that, notwithstanding the availability of tickets, the requirements of Clause 19.1 of the Code should have been well known to the congress department. In that regard the Panel considered that Napp had been badly let down by its staff. With regard to Clause 14.2, however, the Panel noted Napp's submission that the relevant SOP at the time was not sufficiently clear about the need to certify arrangements for international meetings. This was unacceptable and might have been one of the factors which led to the congress department's mistake not being picked up. The Panel considered that overall high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that following the incident, Napp

had rewritten one of the SOPs, to ensure that the need to certify arrangements relating to delegates' attendance at overseas meetings was clear, and had also arranged bespoke training for the congress department.

The Panel noted its comments above and further noted that Napp had given each delegate a letter which stated that the outbound travel arrangements did not comply with the Code. Delegates were further informed that the inbound flights would have to be changed. The Panel noted that the delegates flew home as previously arranged due to clinical/travel arrangements on their return. The Panel considered that the failure of Napp's policies and procedures demonstrated a lack of control in relation to the certification of all of the arrangements for overseas meetings and a lack of awareness of the relevant requirements of the Code. It was of concern that the relevant SOPs were not clear on this matter. The Panel considered that the incident was wholly unacceptable and brought discredit upon or reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case the Panel noted Napp's reference to premium economy tickets. The Code specifically referred only to the provision of economy air travel. There had never been any ruling under the Code regarding the acceptability or otherwise of premium economy air travel. The Code of Practice Appeal Board would make the final decision in that regard if ever a complaint was made and taken to appeal.

Proceedings commenced

1 September 2010

Case completed

27 October 2010