CASE AUTH/1848/6/06

MEDIA/DIRECTOR v JANSSEN-CILAG

Payments offered to journalists

An article in PR Week headed '[a public relations company] in NICE apology for media cash carrot', criticised the activities of the PR company in relation to Eprex (epoetin alfa), a Janssen-Cilag product. In accordance with custom and practice the matter was taken up as a complaint under the Code.

The article stated that ahead of a National Institute for Health and Clinical Excellence (NICE) appeal hearing, a public relations (PR) company emailed reporters to offer them £200 if they wished to attend the hearing. The appeal concerned NICE's rejection of the use of erythropoietins for chemotherapy-induced anaemia.

The Panel noted that there was a contractual agreement between Janssen-Cilag (via Johnson & Johnson) and the PR company. Janssen-Cilag had submitted that the PR company's actions in this case had gone beyond that agreement. In the Panel's view, however, companies were responsible for the actions or omissions of their agents, when acting on their behalf, even if such were contrary to the agreement which existed between the two. If this were not so then it would be possible for agents to undertake any activity beyond the scope of contractual agreements, on behalf of a company, which the company could not do itself, and so avoid the restrictions of the Code.

Although Janssen-Cilag knew nothing of it, the PR company whilst in effect acting for Janssen-Cilag had offered to pay journalists to attend a meeting. The Panel considered that Janssen-Cilag was responsible under the Code. Janssen-Cilag had been let down by its agent. The Panel considered that high standards had not been maintained. Breaches of the Code were ruled including a breach of Clause 2 as the Panel considered that the offer to pay journalists to attend a meeting brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Upon appeal by Janssen-Cilag the Appeal Board noted that the agreement between the PR company and Janssen-Cilag in the UK derived from a global agreement originating from Johnson & Johnson in the US. The Appeal Board considered, however, that in the UK there was insufficient clarity locally on both sides of the PR company's responsibilities under the Code. The Appeal Board noted that Janssen-Cilag had run compliance training for the agency and had had conversations about the Code with the agency. However it considered that verbal agreements and assumptions concerning the PR company's detailed knowledge of the Code were insufficient. A formal requirement that all materials be provided to Janssen-Cilag prior to use might have prevented the problem. The Appeal Board considered that Janssen-Cilag had not actively managed its PR agency or taken all reasonable steps to ensure its agent did not breach the Code.

The Appeal Board considered that Janssen-Cilag was, despite being unaware, responsible for the PR company offering to pay journalists to attend a meeting. The Appeal Board considered that high standards had not been maintained and that the offer to pay journalists to attend a NICE meeting bought discredit upon and reduced confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling's of breaches of the Code including the ruling of a breach of Clause 2.

An article in PR Week, 9 June, headed '[a public relations company] in NICE apology for media cash carrot', criticised the activities of a PR company in relation to Eprex (epoetin alfa), a Janssen-Cilag Ltd product. In accordance with custom and practice the matter was taken up as a complaint under the Code.

COMPLAINT

The article stated that ahead of a National Institute for Health and Clinical Excellence (NICE) appeal hearing, a public relations (PR) company sent an email to reporters saying 'As it is possible that the hearing will take up most of the day, and we understand that your time is valuable, we are able to offer £200 (€293) if you wish to attend'. The appeal concerned NICE's rejection of the use of erythropoietins for chemotherapy-induced anaemia.

When writing to Janssen-Cilag, the Authority asked it to respond in relation to Clauses 2, 9.1 and 19 of the Code.

RESPONSE

Janssen-Cilag stated that the article indicated that a PR company had advised that it was working for Ortho Biotech, a division of Janssen-Cilag and part of the Johnson & Johnson group. Eprex had been mentioned for which Janssen-Cilag held the UK marketing authorization.

Janssen-Cilag knew that under the Code pharmaceutical companies were responsible for activities undertaken by their agents. It contended, however, on this occasion that Janssen-Cilag was not in breach of the Code.

Janssen-Cilag explained that the global PR company was retained by Johnson & Johnson (and wholly owned subsidiary companies such as Janssen-Cilag) to work on, *inter alia*, projects related to Eprex. As part of this work, the PR company had assisted Janssen-Cilag to manage issues related to the negative opinion by NICE of the use of epoietins for chemotherapy-induced anaemia. Janssen-Cilag, among others, had appealed this decision; the appeal was scheduled for hearing on Friday, 2 June.

A contractual agreement, 'General Agreement', had existed between Johnson & Johnson and the PR company since January 1999. Within the terms of this General Agreement, Johnson & Johnson included the corporation, its affiliates, subsidiaries, offices and franchises including international affiliates, subsidiaries, offices and franchises. The PR company

included its offices, subsidiaries and affiliates including international offices, subsidiaries and affiliates. Thus within the terms of this contractual framework, activities undertaken between the PR company and Janssen-Cilag within the UK were bound by the terms of this General Agreement.

Within the General Agreement was a further document, the 'Work Order Agreement', which constituted the mandatory model for all project assignments between the PR company and Johnson & Johnson.

Prior to the NICE appeal on 2 June, Janssen-Cilag found out through a news wire report that a PR agency had offered journalists cash to attend the NICE erythropoietin appeal. The report stated that the PR company had emailed journalists telling them that 'as it is possible that the hearing will take up most of the day, and we understand that your time is valuable, we are able to offer £200 if you wish to attend'.

This financial incentive to attend was made known to NICE and its chairman publicly condemned it and in a broader media statement added that 'it is disappointing that a PR firm finds it necessary to offer financial incentives for journalists to attend NICE public appeal hearings'.

Immediately Janssen-Cilag became aware of this news report, commentary was made in respect of the following:

1 that offering cash incentives to attend public hearings was entirely inappropriate,

2 that whilst acknowledging a PR company worked on the company's behalf, that Ortho Biotech was not aware of, nor did it sanction the offering of payments.

Following the press reports, the chief executive of the PR company in the UK emailed a retraction to the journalists who had been offered a payment to attend the NICE appeal hearing stating:

1 that the matter was a serious misinterpretation of the PR company policy,

2 stressing that the action took place without the knowledge of its client, Ortho Biotech and that such activity would not have received its sanction,

3 noting that NICE appeal hearings had been freely open to the press and public since October 2004.

The chief executive of the PR company in the UK contacted the chairman of NICE directly and apologised. Additionally, a senior executive from Johnson & Johnson in Europe also contacted the chairman expressing concern that such activity had taken place and apologising. The chairman indicated the matter was closed.

The PR company accepted responsibility for its actions, blaming human error, and re-affirming publicly that its client (Ortho Biotech/Janssen-Cilag) was not aware nor would have sanctioned such activities.

In respect of Clause 9.1, Janssen-Cilag asserted that with regard to its own actions high standards were maintained. The PR company publicly stated that Janssen-Cilag was unaware of its offer to pay journalists and that Janssen-Cilag would not have sanctioned such payment. These comments were made on the basis of the agreement between Janssen-Cilag as a subsidiary company of Johnson & Johnson, and the General Agreement which existed between the PR company and Johnson & Johnson:

1 Within the General Agreement and in particular the provision of services within that document it explicitly stated that '[the PR company] covenants that it will abide by all applicable laws and regulations in the exercise of any work it may do for the Client'.

2 The work order agreement (previously stated as the mandatory model for all project assignments between the PR company and Client [Johnson & Johnson Company]) specifically outlined a description of activities undertaken in preparation for the NICE appeal and demonstrated due diligence by Janssen-Cilag in respect of contractual work expected to be carried out by the PR company.

Additionally, as a matter of practice, Janssen-Cilag required all of its contractors to participate in a company run training session so they were familiar with the company's code of ethics and guidelines as well as local laws and regulations. The PR company staff had undertaken such training. Therefore Janssen-Cilag expected agents or contractors operating on its behalf to comply fully with the appropriate laws and regulations, and failure to do so was considered a serious breach of contractual obligation.

Janssen-Cilag therefore contended that with respect to the contractual arrangements which allowed the PR company to act as agent for Janssen-Cilag, it demonstrated a high degree of integrity. The actions leading to this complaint were the errant actions of an individual employee of the PR company. This in no way detracted from the due diligence undertaken by Janssen-Cilag. It therefore denied a breach of Clause 9.1.

With regard to Clause 2, Janssen-Cilag reiterated the points above in relation to Clause 9.1. The company further noted that the article in question clearly stated that the PR company had blamed human error for what it described as a total breach of policy. Additionally, the UK chief executive for the PR company also stated that the offer to pay journalists was not something the client knew about and was a mistake by an individual; again clearly stating that this was a result of a failure of one person to follow company procedure which had resulted in a serious breach of policy.

Janssen-Cilag submitted that this had been an isolated (albeit serious) breach of the PR company's policy and procedure. In the news article in question, the author centred the blame on the PR company rather than Ortho Biotech/Janssen-Cilag, as indeed did the chairman of NICE who stated 'it is disappointing that a PR firm finds it necessary to offer financial incentives for journalists to attend NICE public appeal hearings'. The discredit therefore was not aimed at the pharmaceutical industry; if it was aimed anywhere it was at the PR industry.

The Code gave examples of activities that were likely to be in breach of Clause 2; these included the conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and serious nature within a short period of time. Within this framework, accepting that although the incident was serious and that the PR company was indeed Janssen-Cilag's agent, Janssen-Cilag submitted that the incident was isolated and reiterated the strong contractual arrangements it had with the PR company to ensure compliance with laws and regulations. Further Janssen-Cilag also reiterated the PR company's own admission that the incident occurred due to the actions of an individual acting in breach of company policy.

While admitting that journalists had been offered a payment, which was indeed a serious breach of policy, by way of the arguments expounded above, Janssen-Cilag sought to mitigate culpability and thus denied a breach of Clause 2.

With regard to Clause 19 Janssen-Cilag appreciated that NICE appeals were open to journalists and indeed the general public and had already stated that it considered it inappropriate that journalists were offered a payment to attend. As previously stated, Janssen-Cilag was not aware of the offer and hence could not answer specifically with respect to Clause 19 or any of its sub clauses. Again Janssen-Cilag argued that such actions were outside of the policy framework and contractual obligation that the PR company had to Janssen-Cilag, and hence again denied breach of Clause 19.

PANEL RULING

The Panel noted that there was a contractual agreement between Janssen-Cilag (via Johnson & Johnson) and a PR company. Janssen-Cilag had submitted that the PR company's actions in this case had gone beyond that agreement. In the Panel's view, however, companies were responsible for the actions or omissions of their agents, when acting on their behalf, even if such acts or omissions were contrary to the agreement which existed between the two. If this were not so then it would be possible for agents to undertake any activity beyond the scope of contractual agreements, on behalf of a company, which the company could not do itself, and so avoid the restrictions of the Code.

The supplementary information to Clause 20.2 stated, *inter alia*, that meetings organized for or attended by journalists must comply with Clause 19. The supplementary information to Clause 19.1 stated that delegates must not be offered compensation merely for their time spent at meetings. Although Janssen-Cilag was unaware of the specific activity, the PR company whilst in effect acting for Janssen-Cilag had offered to pay journalists to attend a meeting. The Panel considered that Janssen-Cilag was responsible under the Code. Janssen-Cilag had been let down by its agent. The Panel ruled a breach of Clause 19.1 of the Code. This ruling was accepted by Janssen-Cilag. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel considered that the offer to pay journalists to attend a meeting brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 of the Code was ruled.

APPEAL BY JANSSEN-CILAG

Janssen-Cilag appealed the Panel's rulings of breaches of Clauses 2 and 9.1 of the Code. In particular, the company considered that it had acted entirely properly in respect of contractual arrangements with the PR company, and failed to understand how, because of the unauthorised action of an employee from the PR company, it had been found to be in breach of Clause 2 of the Code.

Janssen-Cilag submitted that the complaint had arisen from the inexplicable and unforeseeable actions of one errant individual within the PR company. The agency had confirmed in writing that the company had not requested, nor was aware, of the individual's actions. Furthermore, that individual had acted in clear contravention of both Janssen-Cilag policies and those of the PR company.

Janssen-Cilag understood that the Panel had based its ruling on Clause 1.2 of the Code where the definition of promotion included any action undertaken by a pharmaceutical company, or with its authority, which promoted the prescription, supply, sale or administration of its medicines. This had been interpreted to mean that companies were responsible for PR agencies acting on their authority.

Janssen-Cilag submitted that it was clear and logical that companies should usually be accountable for the actions of PR agencies acting on their authority. Without this provision, companies could avoid compliance with the Code by merely instructing PR agencies to undertake tasks for them. However, a company should not necessarily be accountable for the actions of its PR or advertising agency when it was clear that neither the company, nor indeed the relevant agency, intended the agency to act in the way that it did. Janssen-Cilag noted previous relevant cases, Case AUTH/1087/10/00 and Case AUTH/1028/6/00 in which it was accepted that there were circumstances where an advertising agency might be at fault and not the pharmaceutical company, which had taken reasonable steps to comply with the Code.

Janssen-Cilag submitted that the same rationale applied now. In the current case, Janssen-Cilag took all reasonable steps to avoid a breach of the Code and to control the actions of its PR agency. There was a contract in place in which the PR agency covenanted to abide by all applicable laws and regulations in the exercise of any work it did for the company. Janssen-Cilag had even taken the additional precautionary step of performing due diligence in respect of the agency's policies.

Janssen-Cilag submitted that the employee who offered to pay journalists had acted contrary to the PR company's policies. There could be no suggestion that he/she had acted on the authority of Janssen-Cilag or the PR agency. The employee's action had been described very specifically by the company as errant. The employee's actions were thus unforeseeable and unpredictable, and there were no

steps that it could have taken to prevent such inexplicable action being taken by a maverick employee of a third party.

Janssen-Cilag submitted that it had acted honourably and openly at every stage of this situation. The action taken by the company, and the PR agency, immediately upon becoming aware of the situation, was swift and strong. The PR agency explained the situation to NICE, which declared the matter closed. It was hard to reconcile this with the Panel's ruling that Janssen-Cilag's conduct had brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Janssen-Cilag submitted that with respect to high standards, should a contract stipulate that relevant codes of practice were adhered to, then it expected its agents to adhere to them. Specifically for the future no payments should be offered to journalists to attend a meeting, however this was already covered in respect of reference to Clauses 19 and 20.2 and the supplementary information. Short of stating every conceivable scenario in advance within a contract Janssen-Cilag failed to understand how it had not maintained high standards (Clause 9.1).

Notwithstanding the above Janssen-Cilag also failed to understand what further reasonable steps it could take to prevent completely unexpected actions of an errant individual acting contrary to his/her own company's policies and in breach of the contractual obligation to it. Janssen-Cilag therefore could not give a meaningful undertaking that similar breaches of the Code would not occur at some future time despite of its due diligence. Such actions were entirely out of its, or indeed any other pharmaceutical company's, control.

COMMENTS FROM THE JOURNALIST

The journalist made no comment.

APPEAL BOARD RULING

The Appeal Board noted that there was a contractual agreement between Janssen-Cilag (via Johnson & Johnson in the US) and a PR company. Janssen-Cilag submitted that the PR company's actions had gone beyond that agreement. The Appeal Board considered that as the agreement between the PR company and Janssen-Cilag in the UK derived from a global agreement, there was insufficient clarity locally on both sides of a PR company's responsibilities under the UK Code. The Appeal Board noted that Janssen-Cilag had run compliance training for the agency and had had conversations about the Code with the agency. However it considered that verbal agreements and assumptions concerning the PR company's detailed knowledge of the Code were insufficient. A formal requirement that all materials be provided to Janssen-Cilag prior to use might have prevented the problem. The Appeal Board considered that Janssen-Cilag had not actively managed its PR agency or taken all reasonable steps to ensure its agent did not breach the Code.

The Appeal Board noted that Janssen-Cilag accepted the Panel's ruling of a breach of Clause 19.1 of the Code. It considered that Janssen-Cilag was, despite being unaware, responsible for a PR company offering to pay journalists to attend a meeting. The Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a breach of Clause 9.1 of the Code. The Appeal Board considered that the offer to pay journalists to attend a NICE meeting bought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2.

Proceedings commenced **20 June 2006**

Case completed **25 September 2006**