CASE AUTH/2118/4/08

LIFEBLOOD: THE THROMBOSIS CHARITY v BOEHRINGER INGELHEIM

Pradaxa press release

Lifeblood: The Thrombosis Charity complained about a press release about Pradaxa (dabigatran etexilate) which it stated had been issued by a media advisor acting for Boehringer Ingelheim.

Lifeblood stated that the press release appeared to have come from it. Lifeblood did not, nor would it, its trustees or its medical director, ever issue any press release which endorsed or appeared to endorse a specific product.

In other press releases concerning Pradaxa, Lifeblood discussed the area generally and did not endorse the product directly.

It was the policy of Lifeblood to remain independent. When there were advances in the prevention and treatment of thromboembolic disease, the trustees including the medical director took great care not to give specific endorsements. Any statements sought from the trustees, or the medical director, were deliberately couched in neutral terms to welcome the advance but not to endorse the product. No payment was accepted for participating in any press releases, and all releases were vetted to ensure that the neutrality was preserved. Lifeblood, and in particular its medical director, were not given sight of the press release in question, the opportunity to comment on its content or asked for consent to publish the press release.

Three trustees of Lifeblood were health professionals who were active on the National Institute for Health and Clinical Excellence (NICE) committees. NICE was in the midst of determining what the NHS best practice should be in this field.

The impartiality of those trustees, and of Lifeblood, was of paramount importance, for without it the charity's credibility as a lobbying force, and any research it commissioned would be tainted. This was of particular concern when dealing with any of the multinational pharmaceutical companies which were competitively and aggressively pursuing an alternative to warfarin.

Lifeblood's medical director was invited by Boehringer Ingelheim to participate in media interviews, the day that Pradaxa (the new oral anticoagulant) was launched in April 2008. Boehringer Ingelheim was fully aware of the necessity for Lifeblood to remain impartial.

Boehringer Ingelheim offered to pay Lifeblood and its medical director for the time she spent participating in media interviews, but this was declined.

The press release at issue had placed Lifeblood in a very difficult position, for it compromised its apparent integrity and impartiality. Reputation and trust were very hard won, and very easy to lose. In this instance the irresponsible publication of an unauthorised press release had placed its reputation in jeopardy.

This press release was not known about, or sanctioned, by Lifeblood. Its content was completely unacceptable and appeared designed to cynically manipulate public opinion and market forces – at the expense of Lifeblood and its medical director – for the benefit of those promoting Pradaxa.

The Panel noted that it was a clearly established principle under the Code that a company was responsible for the actions of third parties employed on the company's behalf even if that third party acted outside the instructions from the pharmaceutical company.

The Panel considered that Boehringer Ingelheim had been very badly let down by a subcontractor to its agency who had not followed the agreed procedures regarding prior approval of material. This was of serious concern. The agency had subcontracted the media advisor. Neither the agency nor Boehringer Ingelheim knew why the approved press release had been amended without reference or approval from either the agency or Boehringer Ingelheim.

The effect of the actions of the consultant to the agency were extemely serious. Quotations were used in an inappropriate manner ie the quotations did not reflect the meaning of the author and formal permission had not been obtained. Thus the Panel ruled breaches of the Code. The Panel also considered that the quotation attributed to Lifeblood's medical director was not in line with the authorized indications for Pradaxa as it did not state that it was for use after elective surgery; the material was thus misleading and inaccurate in this regard. A breach of the Code was ruled.

The Panel considered that it was particularly important when working with third parties such as patient organisations that all materials were in accordance with the Code. This was even more important when working on a new product as all such materials had to be prevetted by the Medicines and Healthcare Products Regulatory Agency (MHRA).

The Panel noted the circumstances of this case. Boehringer Ingelheim had a procedure for approving press releases and its contract with the agency stated that material had to be submitted to the company for written approval before release. The contract further stated that the agency should comply with all codes of practice. According to Boehringer Ingelheim's submission the agency had used an experienced subcontractor, trained on the Code, who had acted entirely outside the contract and without the knowledge of either the agency or Boehringer Ingelheim. It was difficult to see what more Boehringer Ingelheim could have done. The Panel considered that as Boehringer Ingelheim had procedures and processes in place to ensure compliance with the Code and had been so very badly let down by a third party there was no breach in relation to the requirements to maintain high standards and not to bring discredit upon the pharmaceutical industry.

Lifeblood: The Thrombosis Charity complained about a press release about Pradaxa (dabigatran etexilate) which it stated had been issued by a media advisor acting for Boehringer Ingelheim Limited.

Paraxa was indicated for the primary prevention of venous thromboembolic events in adult patients who had undergone elective total hip replacement surgery or total knee replacement surgery.

COMPLAINT

Lifeblood stated that the press release appeared to have come from it. Lifeblood did not, nor would it, its trustees or its medical director, ever issue any press release which endorsed or appeared to endorse a specific product.

In other press releases concerning Pradaxa, Lifeblood discussed the area generally and did not endorse the product directly. For example, in one of the press releases from Boehringer Ingelheim the following was stated:

> '[A named] Consultant Haematologist and Medical Director of the UK thrombosis charity, Lifeblood commented,
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> "The prevention of blood clots with blood thinners after orthopaedic surgery is not done well in the UK. One of the problems is that the current blood thinners can only be given as an injection. We therefore very much welcome the arrival of a tablet for adults undergoing elective hip and knee surgery. The need for, and the potential impact of a generally well tolerated oral anticoagulant that does not require monitoring is profound"'.

Lifeblood was an independent charity founded just over five years ago; its objectives were to increase awareness of thrombosis among the public, and health professionals, and to raise research funds to improve patient care through improved prevention and treatment of venous thromboembolic disease. Lifeblood worked closely with the National Institute for Health and Clinical Excellence (NICE), an All Party Parliamentary Health Select Committee, the Department of Health, the Government, the Scottish and Welsh Assemblies, National Health trust hospitals and primary care trusts in the furtherance of these aims.

It was the policy of Lifeblood to remain independent. When there were advances in the prevention and treatment of thromboembolic disease, the trustees including the medical director took great care not to give specific endorsements. Any statements sought from the trustees, or the medical director, were deliberately couched in neutral terms to welcome the advance but not to endorse the product. No payment was accepted for participating in any press releases, and all releases were vetted to ensure that the neutrality was preserved. Lifeblood, and in particular its medical director, were not given sight of the press release in question, the opportunity to comment on its content or asked for consent to publish the press release.

Three trustees of Lifeblood were health professionals who were active on NICE committees. NICE was in the midst of determining what the NHS best practice should be in this field.

The impartiality of those trustees, and of Lifeblood, was of paramount importance, for without it the charity's credibility as a lobbying force, and any research it commissioned would be tainted. This was of particular concern when dealing with any of the multinational pharmaceutical companies who were competitively and aggressively pursuing an alternative to warfarin.

Lifeblood's medical director, was invited by Boehringer Ingelheim to participate in media interviews, the day that Pradaxa (the new oral anticoagulant) was launched in April 2008. Boehringer Ingelheim was fully aware of the necessity for Lifeblood to remain impartial.

Boehringer Ingelheim offered to pay Lifeblood's medical director for the time she spent participating in media interviews, but this was declined for it would cause a conflict of interest which would compromise her status as an independent consultant haematologist within NICE and as medical director of Lifeblood. Boehringer Ingelheim had offered to make payments direct to Lifeblood, but this offer would also be declined, for it would compromise the integrity of the charity.

The press release at issue had placed Lifeblood in a very difficult position, for it compromised its apparent integrity and impartiality. Reputation and trust were very hard won, and very easy to lose. In this instance the irresponsible publication of an unauthorised press release had placed its reputation in jeopardy.

This press release was not known about, or sanctioned, by Lifeblood. Its content was completely unacceptable and appeared designed to cynically manipulate public opinion and market forces – at the expense of Lifeblood and its medical director – for the benefit of those promoting Pradaxa.

When writing to Boehringer Ingelheim the Authority asked it to respond in relation to Clauses 2, 9.1, 11.2, 11.3 and 20.2 of the Code.

RESPONSE

Boehringer Ingelheim stated that it planned a media awareness campaign at the time of launch of Pradaxa and contracted an agency, to provide media contact and implement the campaign.

Two press releases, one for the medical profession (ref DBG1128) and one for the public (ref DBG1129) were the core items of this campaign and Boehringer Ingelheim additionally produced disease awareness (ref DBG1130) and Pradaxa related fact sheets (ref DBG1131) to be distributed alongside the press releases to provide additional information if needed. Within the two press releases quotations from Lifeblood's medical director, for which she had given her prior approval to the agency, were faithfully reproduced.

All of these press materials were factual and presented in a balanced way and were approved by Boehringer Ingelheim according to the standard operating procedure (SOP) Approving Communication Materials. In addition, all press materials were pre-vetted by the MHRA and its comments were incorporated into the final versions.

Approved press releases were released to the agency on headed Boehringer Ingelheim paper and it was clear that the two press releases were issued by Boehringer Ingelheim.

The contract between Boehringer Ingelheim and the agency clearly stated the agency's responsibility in activities undertaken on behalf of Boehringer Ingelheim. Specifically, the contract stated in:

> 'Clause 4.2: All campaign materials are to be submitted by the Agency for Boehringer Ingelheim approval. Such approval is the Agency's authority to proceed.'
>
> 'Clause 4.5: The Agency commits to comply with all relevant legislation and codes of practice.' (The codes were defined to include the ABPI Code, amongst others).
>
> 'Clause 5.4: The Agency warrants that it will use due skill and a professional standard of care.'

The agency subcontracted a media advisor to conduct this media activity on its behalf. The media advisor had worked for many years as a healthcare media relations consultant and was previously public relations director at another pharmaceutical company. The media advisor was not directly employed by Boehringer Ingelheim.

The media advisor, for reasons that were entirely unclear to Boehringer Ingelheim and to the agency, changed the approved press release without reference to Boehringer Ingelheim or the agency, without seeking any form of approval for the amended release. This altered press material was the subject of the complaint and was sent to the Daily Telegraph, the Daily Express, the Daily Mail and the BBC. The Daily Mail received material headed 'from thrombosis charity Lifeblood' and the BBC received material headed 'from Lifeblood'. This altered material was neither created nor approved by Boehringer Ingelheim. Other news organisations received the approved press release. At no stage during the creation and finalisation of the approved press releases did Boehringer Ingelheim alter or ask the agency to alter Lifeblood's medical director's quotation, without her permission.

Therefore, in relation to clause 4.2 of the contract referred to above, no approval was issued by Boehringer Ingelheim for the agency, or its subcontractor, to proceed with disseminating this unauthorised press material.

Boehringer Ingelheim disagreed that the material was issued by '[a named media advisor] acting on behalf of Boehringer Ingelheim', when the media advisor and/or the agency were acting totally outside the scope of their authority and instructions. Boehringer Ingelheim was extremely disappointed by these events and could not understand why an experienced consultant such as the media advisor would have changed the approved release, or issued an amended version without seeking the approval of Boehringer Ingelheim.

Since Boehringer Ingelheim was made aware of this situation the following actions had been taken:

- The agency required to remove the media advisor from PR activity.
- The agency asked for records of the media advisor to ascertain to whom the press material was sent.
- Meeting between Lifeblood's medical director, the agency and Boehringer Ingelheim to fully understand events.
- Meeting with Lifeblood trustees, the agency and Boehringer Ingelheim to understand their concerns.
- Communication with Lifeblood, sharing with it an internal Boehringer Ingelheim statement to be used to address enquiries regarding relationship of Boehringer Ingelheim and Lifeblood.
- The agency directed to have no direct contact with Lifeblood during the complaint process.
- Lifeblood informed about the agency's investigation.
- Boehringer Ingelheim took initial steps to contact the ABPI itself, because of concerns about the unauthorised materials.

Boehringer Ingelheim strongly believed that throughout the process of preparation, approval and release of its press releases it had maintained high standards and that through its procedures had complied with the Code. If, which was not admitted, there was found to have been a breach of the Code, Boehringer Ingelheim did not accept that it was party to any act, omission or default which led to such a breach.

In spite of robust internal approval processes for these press releases and a clear contractual requirement that the agency get all materials approved, and an explicit requirement that it comply with the Code, a press release was issued that had been subsequently amended after final certification by Boehringer Ingelheim.

In the ordinary course, if a pharmaceutical company instructed an agency to issue a press release, knowing that it did not comply with the Code, one would fully expect a breach of the Code to be found. However, the facts of this case were materially different. In this case, Boehringer Ingelheim did everything to comply with the legal and regulatory requirements. It was therefore difficult to see how Boehringer Ingelheim could have prevented this irresponsible and totally unexpected activity.

In light of these events Boehringer Ingelheim would undertake an internal review to investigate if and how contracts etc with agencies could be amended, or if other action could be taken to reduce the risk of a similar situation ever arising again.

Boehringer Ingelheim submitted that, if a breach of the Code occurred, it was due to the agency and/or its sub-contractor acting totally beyond the scope of their or his authority and brief, effectively being 'on a frolic of their or his own'. In such circumstances, Boehringer Ingelheim should not be found to be in breach of the Code.

If, which was not admitted, a breach of the Code was found to have occurred, despite the absence of fault on the part of Boehringer Ingelheim, the company trusted that it would be treated in the most lenient manner possible, having regard to the mitigating factors referred to above.

In relation to Clause 2, Boehringer Ingelheim submitted that it had not brought discredit to, or reduced confidence in the pharmaceutical industry. The unauthorised press materials were issued without any reference to, or knowledge of, Boehringer Ingelheim and without the knowledge of the agency, by an experienced person who was thought to be (and given their background and recent compliance training with the agency should have been) fully aware of the Code. As soon as Boehringer Ingelheim knew of the circumstances it investigated the matter and apologised to Lifeblood for what had occurred. Indeed, Boehringer Ingelheim had already made a preliminary contact with the ABPI before the complaint was received.

Boehringer Ingelheim held Lifeblood, its trustees and medical director in the highest regard and would not wish to do anything to affect their impartiality and integrity. Boehringer Ingelheim had been scrupulous in ensuring that all necessary approvals were obtained and was satisfied that the authorised press releases complied with the Code and all other requirements. Since the matter came to light, Boehringer Ingelheim had acted promptly and in the best interests of Lifeblood and the industry.

In this regard, Boehringer Ingelheim felt it must deal with two particular points made by Lifeblood in its complaint.

The first was where Lifeblood referred to the 'irresponsible publication of an unauthorised article'. Boehringer Ingelheim objected to the reference of 'irresponsible' being used in relation to a complaint against Boehringer Ingelheim. As it hoped it had shown, Boehringer Ingelheim had behaved in a very responsible manner throughout and deeply regretted the media advisor's actions which were taken without Boehringer Ingelheim's knowledge or authority.

Secondly, Lifeblood referred to the content of the press materials as appearing to be 'designed to cynically manipulate public opinion and market forces – at the expense of Lifeblood and its [medical director] – for the benefit of those promoting Pradaxa'. Boehringer Ingelheim had no such intention or design and it almost went without saying that the actions of the agency and/or the media advisor, far from benefiting Boehringer Ingelheim, had caused significant damage.

As regards Clause 9.1, Boehringer Ingelheim's actions, both in relation to the approval process for the authorised press releases and once it became aware of the unauthorised press materials, demonstrated its commitment to high standards. If, having done everything possible to ensure that the highest standards were maintained, Boehringer Ingelheim was badly let down by a trusted agency and/or its sub-contractor, who had acted without authority and out of character, Boehringer Ingelheim suggested that it would not be appropriate to find that it had failed to maintain high standards.

Boehringer Ingelheim took great care to comply with the requirements of Clauses 11.2 and 11.3, aware of the importance of only using accurate quotations from an accredited source, as was reflected in the authorised press releases. It was not clear to Boehringer Ingelheim what more it could have been done to ensure that only the quotations, as stated, were used, in the form presented, but it had to acknowledge that, due to the wholly unauthorised actions of the media advisor, quotations were used in an inappropriate manner.

In relation to Clause 20.2, Boehringer Ingelheim took great care to prepare two distinct press releases, one

for the public and the other for the medical profession. Boehringer Ingelheim was scrupulous to ensure that the requirements of the Code were met regarding information provided to the public. However, it acknowledged that, despite its best efforts, unauthorised actions resulted in inappropriate information being made available for use.

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Following receipt of the complaint, an email from the media advisor to the complainant (dated 17 May) was forwarded to the Authority.

This email referred to the the complaint and encouraged withdrawal of the complaint. It referred to helping Lifeblood and its medical director achieve the best possible coverage for National Thrombosis Week. The author referred to himself as a media advisor and that he would be contacting other parties about the matter.

A copy of this email was provided to Boehringer Ingelheim Limited.

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FURTHER COMMENTS FROM THE COMPLAINANT

In response to a request from the Panel the complainant confirmed that neither the agency nor the media advisor worked for Lifeblood independently of any work for Boehringer Ingelheim. The original press release came to the complainant's attention via a friend who knew how hard Lifeblood worked to remain independent of any possibility of being influenced by pharmaceutical companies and had been surprised to see it, and assumed Lifeblood had not authorised it.

FURTHER COMMENTS FROM THE RESPONDENT

Boehringer Ingelheim confirmed it was not aware that the media advisor had emailed Lifeblood's medical director until Lifeblood's medical director sent it a copy of the correspondence on 19 May 2008. Immediately Boehringer Ingelheim's lawyers sent a letter to the media advisor by email and hard copy on 20 May 2008 stating that 'Boehringer Ingelheim Limited totally disassociates itself from the email and its contents'. The letter also stated 'Our client will not comment on the contents of your email other than to say it is wholly inappropriate and unprofessional, particularly given your apparent experience in the medical and pharmaceutical areas'. Furthermore, Boehringer Ingelheim required an undertaking from him that he would neither explicitly nor implicitly state that he acted on behalf of Boehringer Ingelheim. The agency had no prior knowledge of the media advisor's email to Lifeblood's medical director, although a copy had been forwarded to it by Boehringer Ingelheim. Since 26 April 2008 the media advisor had not acted on behalf of the agency and in no way represented that company's views.

A copy of the letter to the media advisor was also sent to Lifeblood's medical director and the Chairman of the Board of Trustees of Lifeblood by email on 21 May 2008. This was acknowledged by Lifeblood's medical director. The letter was sent to the media advisor on 20 May 2008, but no response had been received. Boehringer Ingelheim was therefore unable to include any comments from the media advisor within this response.

Boehringer Ingelheim continued to be extremely disappointed by these events and could not understand why an experienced consultant such as the media advisor communicated with Lifeblood's medical director in this way.

In relation to the question whether the agency also worked separately for Lifeblood, the agency had responded thus:

> 'We confirm that [the agency] has never worked separately with Lifeblood and has no contract with Lifeblood the charity.
>
> In early April 2008, [the agency] was contacted by [Lifeblood's medical director] who asked whether it would be able to assist Lifeblood with public relation services for National Thrombosis Week. [The agency] made it clear to Lifeblood that it would not be able to take on any separate project for Lifeblood without consent of its existing client, Boehringer Ingelheim (BI). BI confirmed its approval to [the agency] undertaking work for Lifeblood, however, no contract has been entered into with Lifeblood with [the agency] for the provision of such services and no work undertaken'.

PANEL RULING

It was a clearly established principle under the Code that a company was responsible for the actions of third parties employed on the company's behalf even if that third party acted outside the instructions from the pharmaceutical company. Clause 20.6 of the Code made it clear that companies were responsible for information about products issued by their public relations agencies.

The Panel considered that Boehringer Ingelheim had been very badly let down by a subcontractor to its agency who had not followed the agreed procedures regarding prior approval of material. This was of serious concern. The agency had subcontracted the media advisor. Neither the agency nor Boehringer Ingelheim knew why the approved press release had been amended without reference or approval from either the agency or Boehringer Ingelheim.

The effect of the actions of the consultant to the agency were extemely serious. Quotations were used in an inappropriate manner ie the quotations did not reflect the meaning of the author and formal permission had not been obtained. Thus the Panel ruled breaches of Clauses 11.2 and 11.3 of the Code. The Panel also considered that the quotation attributed to Lifeblood's medical director was not in line with the authorized indications for Pradaxa as it did not state that it was for use after elective surgery; the material was thus misleading and inaccurate in this regard. A breach of Clause 20.2 was ruled.

The Panel considered that it was particularly important when working with third parties such as patient organisations that all materials were in accordance with the Code. This was even more important when working on a new product as all such materials had to be prevetted by the Medicines and Healthcare Products Regulatory Agency (MHRA).

The Panel noted the circumstances of this case. Boehringer Ingelheim had a procedure for approving press releases and its contract with the agency stated that material had to be submitted to the company for written approval before release (clause 4.2). The contract further stated (clause 4.5) that the agency should comply with all codes of practice. According to Boehringer Ingelheim's submission the agency had used an experienced subcontractor, trained on the Code, who had acted entirely outside the contract and without the knowledge of either the agency or Boehringer Ingelheim. It was difficult to see what more Boehringer Ingelheim could have done. The Panel considered that as Boehringer Ingelheim had procedures and processes in place to ensure compliance with the Code and had been so very badly let down by a third party there was no breach of Clauses 9.1 and 2 of the Code.

Complaint received **25 April 2008**

Case completed **27 June 2008**