CASE AUTH/2333/7/10

ANONYMOUS v BAYER

Promotion of Levitra

An anonymous and non contactable complainant complained about a four page document entitled 'Prescribing Policy: Vardenafil as first choice for erectile dysfunction' which stated that it was supported by an educational grant from Bayer Schering Pharma. Bayer Schering Pharma marketed Levitra (vardenafil).

The document briefly discussed the prevalence, cause and general treatment of erectile dysfunction and thereafter discussed Levitra in relation to national clinical guidelines, its evidence base and comparative cost savings.

The complainant stated that he had received the document unsolicited with no prescribing information enclosed. The top of page two clearly referred to Levitra and its licensed indication.

The detailed response from Bayer is given below.

The Panel noted that the document made very positive clinical and cost claims about vardenafil. A statement at the bottom of the front page included 'Supported by an educational grant from Bayer Schering Pharma. No editorial input from Bayer Schering Pharma ….'. Eight authors were listed on the back page. The Panel noted Bayer's submission that the mailing was initiated by a third party consultancy, and that it had no input into the content of the document. The Panel noted that whether a company was responsible for sponsored material depended on a number of factors. That the material was initiated by a third party did not, in itself, absolve the company from responsibility under the Code.

The Panel considered that there was no arm's length arrangement between the provision of the sponsorship and the generation of the prescribing policy. Bayer had accepted the consultancy's commercial proposal to write, secure named authors for, and publish guidance on the use of Levitra. The extract of the agreement between Bayer and the consultancy provided that the consultancy must ensure that the policy document was acceptable, *inter alia,* to Bayer. It thus appeared that, contrary to Bayer's submission, it had editorial control. The agreement and the overall arrangements were such that the consultancy had, in effect, operated as the company's agent in the generation of the material and Bayer was thus responsible for its content.

The Panel was very concerned about Bayer's submission that as the material was distributed to medicines managers who were not health professionals *per se* the material was not promotional. The Panel considered that this demonstrated a fundamental lack of understanding of the relevant requirements of the Code. The Code applied not only to material/activity directed at health professionals, but also appropriate administrative staff. Medicines could thus be promoted to medicines managers who were not health professionals so long as the material was relevant to their role and otherwise complied with the Code. The status of the intended audience was relevant but did not in itself determine whether or not the material was promotional; all the circumstances had to be taken into account. Promotion was defined in the Code as any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines.

The Panel noted that the agreement between the parties listed two objectives: to place Levitra as first choice phosphodiesterase inhibitor with primary care organisations and to advocate switches from other phosphodiesterase inhibitors to Levitra. The Panel noted that the material contained very positive clinical and cost claims for Levitra; Bayer had provided the consultancy with a vardenafil price list. The Panel considered that Bayer's submissions that the material was simply distributed on behalf of the authors and that the consultancy requested that the material be so distributed was not an accurate reflection of the arrangements as set out in the agreement. It was envisaged in the agreement at the outset that the material would be distributed by Bayer in the field. This implied promotional use. The mailing list was requested by and screened by Bayer. In the Panel's view the overall arrangements and content of the material were such that it was clearly promotional. The material ought to have borne prescribing information as referred to by the complainant. A breach of the Code was ruled.

During its consideration of this case the Panel was very concerned that the company's response and the overall arrangements demonstrated a fundamental lack of understanding of the requirements of the Code and a lack of control of promotional material. The Panel found it difficult to understand how the material could be seen as anything other that promotional material for which the company was responsible.

The Panel was extremely concerned about the content of the document. The title 'Prescribing Policy: Vardenafil as first choice for erectile dysfunction' implied that Levitra was 'the first choice' which was unacceptable under the Code. The Panel further noted that the document

variously described Vardenafil as a 'safe option' and that it had proven or demonstrated 'efficacy and safety'. All of these claims were contrary to the requirements of the Code which stated, *inter alia*, that the word 'safe' must not be used without qualification. The bullet point 'According to NICE [National Institute for Health and Clinical Excellence] guidance for Type 2 Diabetes vardenafil should therefore become the preferred prescribing option for erectile dysfunction;' implied that NICE had specifically recommended Levitra and that was not so. NICE recommended choosing the medicine with the lowest acquisition cost. The Panel noted that the sole allegation concerned the absence of prescribing information.

Taking all the circumstances into account the Panel decided that the company's conduct in relation to the Code warranted consideration by the Code of Practice Appeal Board and it decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

The Appeal Board considered that Bayer's failure to recognise that the document was in fact wholly unacceptable promotional material was a shocking error of judgement. The Appeal Board was extremely concerned about the content of the document and about Bayer's arrangements. In that regard the Appeal Board noted that Bayer had not provided a copy of the full agreement between it and the consultancy. The Appeal Board considered that the overall arrangements and content of the material demonstrated a fundamental lack of understanding of the requirements of the Code.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Bayer's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted as soon as possible. In addition the Appeal Board decided, given the large number of medicines managers who had been sent the prescribing policy document, that Bayer should take steps to recover the item by writing to each recipient to ask them to, where practicable, return it. This should be done as soon as possible. The Appeal Board requested that the content of the letter be agreed with the Authority before it was sent; the letter should explain the reasons for the Appeal Board's decision. The progress of the steps to recover the document would be discussed at the audit.

On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary.

Upon receipt of the October 2010 audit report the Appeal Board was extremely concerned that Bayer had circulated the material at issue more widely than previously indicated to the Panel and the Appeal Board. The company apologised for the error and explained that it had come to light as a result of the requirement that the material be recovered from those to whom it had been sent. The Appeal Board considered that it was vital that responses to the Authority were accurate and gave complete information. The failure to provide comprehensive information was unacceptable. The Appeal Board noted Bayer's submission that the late notification was due to poor communication between the senior managers involved in preparing the response to the PMCPA. The Appeal Board decided that Bayer should be publicly reprimanded for this failure.

The Appeal Board noted Bayer's response that it would implement the recommendations in the report as soon as possible and that it had appointed a corrective and preventive action team to do this. The Appeal Board was concerned about the profile of the medical department with regard to compliance issues and considered that it should be raised.

The Appeal Board was concerned about the audit report particularly given that the company had been audited twice in 2007 as a result of another case. The Appeal Board decided that a further audit should be carried out in February 2011. On receipt of that audit report the Appeal Board would consider whether further sanctions were necessary.

Upon receipt of the February 2011 audit report, the Appeal Board noted the progress made since the audit in 2010. It was important that this progress was continued and maintained. The Appeal Board decided that no further action was required.

An anonymous and non contactable complainant submitted a four page document entitled 'Prescribing Policy: Vardenafil as first choice for erectile dysfunction' which stated that it was supported by an educational grant from Bayer Schering Pharma. Bayer Schering Pharma marketed Levitra (vardenafil).

The document briefly discussed the prevalence, cause and general treatment of erectile dysfunction and thereafter discussed Levitra in relation to national clinical guidelines, the National Institute for Health and Clinical Excellence (NICE), its evidence base and comparative cost savings.

COMPLAINT

The complainant stated that he had received the document unsolicited, post marked 'Reading' with no prescribing information enclosed. The top of page two of the mailing made clear reference to Levitra and its licensed indication.

The detailed response from Bayer is given below.

When writing to Bayer the Authority asked it to respond in relation to Clause 4.1 of the Code.

RESPONSE

Bayer explained that the material was initiated by a

third party consultancy as a result of its proposal to write an information document drawing the attention of medicines managers engaged in primary care organisations (PCOs) to NICE guidance regarding the prescribing of phosphodiesterase-5 (PDE5) inhibitors for type 2 diabetics with erectile dysfunction. The cost of such prescriptions was reimbursable under Schedule 2. The NICE guidance was that the PDE5 inhibitor to be prescribed in the first instance should be that with the lowest cost. Due to a recent price change, the lowest cost PDE5 inhibitor was vardenafil and the independent group which produced the prescribing policy, cited that its prescription could potentially make a maximum cost saving per 100,000 population of £38,120.

Bayer stated that it provided financial support to the consultancy for the writing of the material at issue.

The purpose of the document was to provide information for medicines managers in PCOs that would enable PCOs and trusts to make cost savings and help the NHS face its financial challenge of the efficiency savings required by 2013/14.

It was considered that the communication of information regarding NICE guidance and the significant change to an existing medicine, namely the cost reduction of vardenafil, would help primary care trusts (PCTs) with their budgets. The distribution of the document was not intended to be a means of promoting Levitra to health professionals.

Bayer distributed the document on behalf of the independent authors to 1,665 medicines managers, engaged in PCOs. The mailing addresses were provided by a third party provider. Particular care was taken so that these PCO medicines managers would receive the document. In some cases such managers might also be clinicians and so the mailing list was purposefully screened to ensure that the document was addressed to individuals in their capacity as medicines managers. This was done so that the distribution would not be to health professionals *per se* and therefore constitute promotion.

Bayer stated that it had no input into the content of the prescribing policy.

Bayer explained that the consultancy coordinated and facilitated the writing by an independent group of non-clinical authors who were medicines managers in PCOs. Bayer provided financial support but had no influence in the selection of the authors.

The prescribing policy document was an information piece and it was never intended to use it for the purposes of promotion but only to assist PCTs with efficiency savings and budget forecasts. Nor was it intended that this information piece should be adapted in any way to make it a promotional item. For this reason prescribing information was not and could not be added to it. Bayer submitted that the addition of prescribing information to the policy document would have rendered it promotional.

Given that the document was purely for the information of medicines managers engaged in PCOs and was not to be used as a means of promotion to health professionals it was not certified. Consequently there was no certificate of approval. It was simply distributed on behalf of the authors.

The policy document was an information piece which was for, and sent, only to those to whom the information was relevant, namely medicines managers, and not health professionals *per se*.

In response to a request for further information Bayer provided an extract from a letter dated 9 April 2010 to Bayer from its consultancy. It outlined a proposal to produce guidance on the use of vardenafil (prescribing policy document).

The product manager responded to the letter by telephone. A further letter (dated 19 April 2010) from the consultancy formed the basis of the agreement between it and Bayer. Given that the vardenafil policy document was independently written there was no agreement between Bayer and the authors.

Bayer did not provide any product or other information for the authors of the prescribing policy. However Bayer provided its consultancy with a list of the new vardenafil prices.

The consultancy coordinated and facilitated the writing of the prescribing policy document entirely by email. There were no meetings or advisory boards held. The consultancy knew that all the authors had an interest in cost effective prescribing and were engaged in PCOs. The authors were not brought together as a group. A first draft was prepared by the lead author, a head of medicines management, at a named PCT, and circulated by email to the other authors for a series of reviews so that their comments could be incorporated.

The consultancy advised Bayer two years ago about rivaroxaban activities and in 2010 and gave a lecture on PCOs and practice-based prescription groups at an internal Bayer Schering Pharma meeting, it had raised awareness amongst PCTs that had ScriptSwitch to highlight vardenafil as the lowest cost PDE5 inhibitor in line with NICE guidelines.

A thorough analysis of the company's contract database showed that none of the authors had provided any sort of consultancy service to Bayer.

Bayer stated that it received a copy of the final draft from the consultancy on 5 July 2010; one minor typographical error was brought to its attention. Bayer had no editorial input into the document and did not comment on it.

Bayer submitted that the consultancy requested that

the Levitra prescribing policy document should be mailed on behalf of the authors. It was publicised by a mailing in order that the information was made known only to those for whom it was directly relevant ie medicines managers. Again, the prescribing policy document was an information piece and it was never intended to be used for promotional purposes but only to assist PCTs with efficiency savings and budget forecasts. To have publicised the prescribing policy document, for example, as an article or supplement even in a journal with a target audience specifically intended to include medicines managers would have placed it in the public domain. Consequently it would have been potentially accessible to health professionals and members of the public and, as such, the policy would have been promotional.

Bayer asked a third party to provide a list of people involved in medicines management. Given that it was critical that the prescribing policy should only be sent to medicines managers for whom it was directly relevant, in order to assist them in managing budgets and encourage cost effective prescribing, Bayer screened the mailing list rather than delegate the task to a third party service supplier. This was to ensure that it only included recipients who had a medicines management function.

A copy of the envelope was provided. Bayer submitted that there was no accompanying material; the envelope contained only the Levitra prescribing policy and the recipient's address.

PANEL RULING

The Panel noted that the document entitled 'Prescribing Policy: Vardenafil as first choice for erectile dysfunction' made very positive clinical and cost claims about the product. A statement at the bottom of the front page read 'Supported by an educational grant from Bayer Schering Pharma. No editorial input from Bayer Schering Pharma. Date of preparation July 2010'. Eight authors were listed on the back page. The Panel noted Bayer's submission that the mailing was initiated by a third party, a consultancy, and that it had no input into the content of the prescribing policy. The Panel noted that whether a company was responsible for sponsored material depended on a number of factors. That the material was initiated by a third party did not, in itself, absolve the company from responsibility under the Code for its content.

It had previously been decided in relation to material aimed at health professionals that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable it if had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its content, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes. The Panel considered that this statement of principle applied equally to the content of sponsored material aimed at appropriate administrative staff.

The Panel considered that there was no arm's length arrangement between the provision of the sponsorship and the generation of the prescribing policy. The consultancy had sent Bayer a commercial proposal to write, secure named authors for, and publish guidance on the use of Levitra which the company had decided to accept. The Panel noted that it had only been provided with an extract of the agreement between Bayer and the consultancy. Contrary to Bayer's submission that it had no editorial input into the document and did not comment on it, the letter, which formed the basis of the agreement provided that the consultancy must ensure that the policy document was acceptable, *inter alia*, to Bayer. It thus appeared that Bayer had editorial control. The agreement and the overall arrangements were such that the consultancy had, in effect, operated as the company's agent in the generation of the material and Bayer was thus responsible for its content. The Panel considered that this was so irrespective of the subsequent distribution of the material.

The Panel was very concerned about Bayer's submission that as the material was distributed to medicines managers who were not health professionals *per se* the material was not promotional. The Panel considered that this demonstrated a fundamental lack of understanding of the relevant requirements of the Code. The Code applied not only to material/activity directed at health professionals, but also appropriate administrative staff (Clause 1.1 refers). Medicines could thus be promoted to medicines managers who were not health professionals so long as the material was relevant to their role and otherwise complied with the Code. The status of the intended audience was relevant but did not in itself determine whether or not the material was promotional; all the circumstances had to be taken into account. Promotion was defined in Clause 1.2 as any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines.

The Panel noted that the agreement between the parties listed two objectives: to place Levitra as first choice phosphodiesterase inhibitor with PCOs and to advocate switches from other phosphodiesterase inhibitors to Levitra. The Panel noted that the material contained very positive clinical and cost claims for Levitra; Bayer had provided the consultancy with a vardenafil price list. The Panel considered that Bayer's submissions that the material was simply distributed on behalf of the authors and that the consultancy requested that the material be so distributed was not an accurate

reflection of the arrangements as set out in the agreement. It was envisaged in the agreement at the outset that the material would be distributed by Bayer in the field. This implied promotional use. The mailing list was requested by and screened by Bayer. In the Panel's view the overall arrangements and content of the material were such that it was clearly promotional. The material ought to have borne prescribing information as referred to by the complainant. A breach of Clause 4.1 was ruled.

During its consideration of this case the Panel was very concerned that the company's response and the overall arrangements demonstrated a fundamental lack of understanding of the requirements of the Code and a lack of control of promotional material. The Panel found it difficult to understand how the material could be seen as anything other that promotional material for which the company was responsible.

The Panel queried Bayer's submission that there was no accompanying material and the envelope contained only the prescribing policy and the recipient's address. The envelope provided by Bayer, however, was a plain window envelope and thus it appeared that there should have been some other material inside the envelope which bore the recipient's address. The position was unclear.

The Panel was extremely concerned about the content of the document. The title 'Prescribing Policy: Vardenafil as first choice for erectile dysfunction' implied that Levitra was 'the first choice' to treat erectile dysfunction and this implication was unacceptable in relation to the requirements of Clause 7.10 of the Code. The Panel further noted that the summary stated that 'Vardenafil offers an effective, well-tolerated and safe option for the treatment of ED'. A bullet point on page 1 stated '[Vardenafil has] proven efficacy and safety' and another bullet point on page 3 stated 'Vardenafil has demonstrated efficacy and safety'. All of these claims were contrary to the requirements of Clause 7.9 which stated, *inter alia*, that the word 'safe' must not be used without qualification. The bullet point 'According to NICE guidance for Type 2 Diabetes vardenafil should therefore become the preferred prescribing option for erectile dysfunction;' which appeared as part of the Executive Summary on the front page implied that the NICE guidance at issue had specifically recommended Levitra and that was not so. NICE recommended choosing the medicine with the lowest acquisition cost. The Panel noted that the sole allegation concerned the absence of prescribing information.

The Panel noted that it had been provided with part of the agreement that discussed the activity at issue. The Panel considered that Bayer would be well advised to revisit the entire agreement to ensure that any outputs were Code compliant.

Taking all the circumstances into account the Panel decided that the company's conduct in relation to the Code warranted consideration by the Code of Practice Appeal Board and it decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

COMMENTS FROM BAYER

Bayer accepted the Panel's ruling of a breach of Clause 4.1 and, furthermore, that the Panel found that the document would also have been in breach of Clause 7.9 and 7.10. Consequently Bayer apologised to the Authority for this failure of compliance and extended its apologies to the Appeal Board.

Bayer appreciated that this most unfortunate of incidents led to the Panel's concern that it represented a fundamental lack of understanding of the requirements of the Code and a lack of control of promotional material.

Bayer submitted that corporate compliance was of the utmost importance to it. To this end Bayer had a medical governance group and compliance infrastructure designed to prevent such regrettable incidents. Bayer also retained the services of an external compliance consultancy. Nonetheless, on this occasion there had clearly been a fundamental lack of judgement and lack of process control. Bayer recognised the seriousness of this failure of compliance and therefore had undertaken a number of actions:

- The general business unit (business unit head, medical and marketing), medical group and medical governance had met to thoroughly review the case in order to understand how these non-compliant events came about and to prevent future re-occurrences.

- The business unit would formally review medical and educational goods and services and contracts procedures in September 2010.

- An external compliance agency would audit Bayer in September 2010.

- An internal communication had been sent to all business units, including their sales representatives, requiring confirmation that they had read and understood the findings of the Panel in this case. This was being reinforced by the relevant managers addressing the issue directly with their reportees. The communication emphasised the following:

    - The content of an item and the use made of it determined whether or not it was promotional irrespective of the role of the individuals to whom it was targeted.

    - Mailings undertaken on behalf of third parties must be certified in accordance with Bayer's standard operating procedure on Certification of Promotional Items, Non-Promotional Items

and Activities in the same way as any other mailings or activities conducted by Bayer.

Bayer trusted that its submission demonstrated the seriousness with which it regarded this matter and, importantly, that the necessary and appropriate actions had been taken.

Finally, Bayer reiterated its apologies to both the Panel and Appeal Board and emphasised that every endeavour was being made in order to ensure that there was no future recurrence.

APPEAL BOARD CONSIDERATION

The Appeal Board considered that Bayer's failure to recognise that the prescribing policy document was in fact wholly unacceptable promotional material was a shocking error of judgement. The Appeal Board was extremely concerned about the content of the document and about Bayer's arrangements with the consultancy. In that regard the Appeal Board noted that Bayer had not provided a copy of the full agreement between it and the consultancy. The Appeal Board considered that the overall arrangements and content of the material demonstrated a fundamental lack of understanding of the requirements of the Code.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Bayer's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted as soon as possible. In addition the Appeal Board decided, given the large number of medicines managers who had been sent the prescribing policy document, that Bayer should take steps to recover the item by writing to each recipient to ask them to, where practicable, return it. This should be done as soon as possible. The Appeal Board requested that the content of the letter be agreed with the Authority before it was sent; the letter should explain the reasons for the Appeal Board's decision. The progress of the steps to recover the document would be discussed at the audit.

On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary.

FURTHER APPEAL BOARD CONSIDERATION

Upon receipt of the October 2010 audit report the Appeal Board was extremely concerned that Bayer had circulated the material at issue more widely than previously indicated to the Panel and the Appeal Board. The company apologised for the error and explained that it had come to light as a result of the requirement that the material be recovered from those to whom it had been sent. The Appeal Board considered that it was vital that responses to the Authority were accurate and gave complete information. The failure to provide comprehensive information was unacceptable. The Appeal Board noted Bayer's submission that the late notification was due to poor communication between the senior managers involved in preparing the response to the PMCPA. The Appeal Board decided that Bayer should be publicly reprimanded for this failure.

The Appeal Board noted Bayer's response that it would implement the recommendations in the report as soon as possible and that it had appointed a corrective and preventive action team to do this. The Appeal Board was concerned about the profile of the medical department with regard to compliance issues and considered that it should be raised.

The Appeal Board was concerned about the audit report particularly given that the company had been audited twice in 2007 as a result of another case. The Appeal Board decided that a further audit should be carried out in February 2011. On receipt of that audit report the Appeal Board would consider whether further sanctions were necessary.

Upon receipt of the February 2011 audit report, the Appeal Board noted the progress made since the audit in 2010. It was important that this progress was continued and maintained. The Appeal Board decided that no further action was required.

Complaint received	**15 July 2010**
Undertaking received	**8 September 2010**
Appeal Board consideration	**22 September 2010, 10 November 2010, 17 March 2011**
Interim case report published	**29 October 2010**
Case completed	**17 March 2011**