CASE AUTH/2942/2/17 *NO BREACH OF THE CODE*

HEALTH PROFESSIONAL CONSULTANT TO A PHARMACEUTICAL COMPANY v BOEHRINGER INGELHEIM

Online Spiolto advertisement

A complaint was received in a private capacity from a health professional who stated that he/she worked as a consultant to a pharmaceutical company.

The complaint concerned an online advertisement for Spiolto (tiotropium and olodaterol) issued by Boehringer Ingelheim. Spiolto was indicated as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

The complainant stated that although Spiriva was a Boehringer Ingelheim product it had not mentioned the generic name. This was rather important as how else was one supposed to know what Spiolto was better than. The advertisement stated that prescribing information and references were available which, was only partially true as an out of date prescribing information was present, but references were not.

Spiriva was available as both a Respimat device as well as a dry powder inhaler (Handihaler). The complainant stated that he/she was not clear as to which formulation of Spiriva the comparison referred.

The complainant was interested to look at the references to see what the 'better outcomes' were since this was vague and could be anything from quality of life to length of life or number of exacerbations – or indeed something else entirely. But since the references were not present the complainant stated he/she was still none the wiser and did not see how such a vague claim could be substantiated.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that the advertisement published in Pulse, today online, continuously clicked through the five images one after the other, each of the first four images was shown for approximately four seconds before moving to finishing on the fifth image which was then static.

Each image was of a tree showing its roots and with what appeared to be a couple and their dog underneath the tree. The first stated 'SPIOLTO – an advance in COPD care built on the strong roots of Spiriva (tiotropium)'. The second stated 'Superior lung function and less breathlessness vs Spiriva'. The third stated 'Superior quality of life vs Spiriva'. The fourth stated 'Respimat – designed for effective lung delivery' and included an image of the device firing. The final static image stated 'SPIOLTO – from the start of COPD mainenance therapy for better outcomes early on compared to Spiriva' and included an image of the closed device.

As the first banner included the non-proprietary name, tiotropium, immediately adjacent to the first mention of Spiriva the Panel ruled no breach of the Code.

The Panel noted that all five images included a clear, prominent statement as to where the prescribing information, adverse event reporting and references could be found. The Panel noted the complainant's allegation that the prescribing information was out of date where as Boehringer Ingelheim submitted that it was up-to-date. The Panel noted that it was for the complainant to prove his/her complaint on the balance of probabilities. No detail had been provided by the complainant as to why the prescribing information was not up-to-date. The Panel therefore ruled no breach of the Code.

The Panel noted that the advertisement clearly promoted Spiolto Respimat and compared this with Spiriva which was available as a Respimat and Handihaler. The Panel noted Boehringer Ingelheim's submission that the Spiolto clinical trials programme compared Spiolto and Spiriva Respimat and that Spiolto demonstrated statistically significant improvements in lung function, breathlessness and quality of life as stated in the advertisement. The Panel noted that these features appeared in the second and third images with the final image referring to 'Spiolto - From the start of COPD maintenance therapy for better outcomes early on compared to Spiriva'. The fourth banner stated 'Respimat – designed for effective lung delivery'. The Panel noted that although there was no specific mention of the Spiriva device used for the comparison, the fact that the studies used the same device (Respimat) for both medicines meant that readers would not be misled regarding the devices. The Panel thus ruled no breach of the Code. The Panel considered that the claim for 'better outcomes' compared to Spiriva in the final image would be read in relation to the features compared in the advertisement and thus was not misleading. The comparisons were substantiated by the material provided by Boehringer Ingelheim including the Spiolto SPC. The Panel thus ruled no breaches of the Code.

The Panel noted its rulings above and did not consider that Boehringer Ingelheim had failed to maintain high standards. No breach was ruled.

The complainant stated at the time of submitting the complaint that he/she was a health professional who worked as a consultant to Novartis. It had previously been decided, following consideration

by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for intercompany complaints, the employing company would be named in the report. The complainant would be advised that this would happen and be given an opportunity to withdraw the complaint.

This issue came to the fore many years ago when an employee of a pharmaceutical research company complained in a private capacity about a journal advertisement issued by GlaxoSmithKline UK Ltd (Case AUTH/1498/7/03). In Case AUTH/1498/7/03 it was decided that the pharmaceutical research company would be named in the case report whilst making it clear that the complaint was made in a private capacity.

The case preparation manager decided that the principles set out above would apply to consultants. Consultancy status should not be used to circumvent the normal rules for inter-company complaints.

The complainant was advised that if he/she wished to proceed with the complaint in a private capacity Novartis would be named in the case report; and the respondent company would be informed of his/her professional status and the connection with pharmaceutical companies. The complainant so agreed.

Novartis stated that it had no knowledge of, or involvement in, the complaint and did not know the complainant's identity.

The complaint concerned an online advertisement for Spiolto (tiotropium and olodaterol) (ref UK/SPRES-161076) issued by Boehringer Ingelheim Limited and was published by Pulse online. Spiolto was indicated as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant stated that although Spiriva was a Boehringer Ingelheim product it had not mentioned the generic name. This was rather important as how else was one supposed to know what Spiolto was better than. The advertisement stated that prescribing information and references were available using the link (http://spioltouk.cherrythinking.net/ps/), this was only partially true as an out of date prescribing information was present, but references were not.

Spiriva was available as both a Respimat device as well as a dry powder inhaler (Handihaler). The complainant stated that he/she was not clear as to which formulation of Spiriva the comparison referred.

The complainant was interested to look at the references to see what the 'better outcomes' were since this was vague and could be anything from quality of life to length of life or number of exacerbations – or indeed something else entirely. But since the references were not present the complainant stated he/she was still none the wiser and did not see how such a vague claim could be substantiated.

In writing to Boehringer Ingelheim attention was drawn to the requirements of Clauses 4.1, 4.3 7.2, 7.4 and 9.1 of the Code.

RESPONSE

Boehringer Ingelheim explained that the image of the advertisement provided by the complainant was one of a series of five which made up the whole of the advertisement (UK/SPRES-161076) within the website www.pulsetoday.co.uk. Each image was shown for approximately four seconds before ending on the fifth image, which was then static.

The generic name of Spiriva, tiotropium was mentioned within the advertisement. The name of the active ingredient clearly appeared immediately after the first mention of Spiriva. This could be seen in the first image of the advertisement that the complainant sent to the PMCPA and in the enclosed copies of the advertisement. Boehringer Ingelheim therefore submitted that there was no breach of Clause 4.3.

The prescribing information for Spiolto (tiotropium and olodaterol) and references were available from the link on the advertisement. The prescribing information available via the link was indeed the latest version and up-to-date.

For a brief period between 14 February and 2 March 2017, the website hosting the advertisement experienced a technical error where the link for the prescribing information and references had been routing to a version of the prescribing information which did not include the references. The version without references was designed for a static version of the advertisement that would only be displayed if there was a technical issue with the website. This had yet to be displayed if there was a technical issue with the website. This had yet to be displayed on this website. Despite this, all claims were capable of substantiation, as could be seen in the enclosed references. Boehringer Ingelheim therefore submitted there was no breach of Clauses 4.1 or 7.4.

The comparison drawn within the advertisement was between Spiolto and Spiriva. Both formulations of Spiriva, ie the Respimat device and the Handihaler (dry powder inhaler) contained only tiotropium as an active ingredient. In a very large study of more than 17,000 patients it had been unequivocally demonstrated that both formulations had a comparable efficacy and safety profile. In the Spiolto clinical trials programme, Spiolto was comparable to Spiriva Respimat and demonstrated statistically significant improvements in lung function, breathlessness and quality of life as stated in the advertisement. Boehringer Ingelheim therefore submitted that there was no breach of Clauses 7.2 or 7.4.

The claim of an improvement in the outcomes was on the fifth of five images displayed. The outcomes referred to could clearly be seen within images two, three and four of the five. When the whole advertisement was considered, the statement regarding an improvement in outcomes was not ambiguous. References had been provided to demonstrate that the claims were capable of substantiation. Boehringer Ingelheim therefore submitted there was no breach of Clauses 7.2 or 7.4.

As there were no breaches of any of the clauses stated, Boehringer Ingelheim also submitted that there was no breach of Clause 9.1.

In a response to a request for further information Boehringer Ingelheim provided an electronic copy of the rolling banner advertisement.

PANEL RULING

The Panel noted that the advertisement published in Pulse, today online, continuously clicked through the five images one after the other, each of the first four images was shown for approximately four seconds before moving to finishing on the fifth image which was then static. The Panel noted that the supplementary information to Clause 4.1 Electronic Journals stated that the first part of an advertisement in an electronic journal, such as the banner, was often the only part of the advertisement that was seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information could be found. This should be in the form of a direct link. The first part was often linked to other parts and in such circumstances the linked parts would be considered as one advertisement. The Panel noted that the purpose of this supplementary information was, *inter alia*, to help ensure that the prescribing information and other obligatory information were an integral part of the advertisement thus satisfying the requirements of Clause 4.1. If the first part mentioned the product name then this was the most prominent display of the brand name and the non-proprietary name of the medicine or a list of the active ingredients using approved names where such existed must appear immediately adjacent to the most prominent display of the brand name.

The Panel considered that there were differences between a static banner on which one proactively clicked to link to other material including the prescribing information, and a series of images. The length of time that each image was displayed within a series would vary, could not be influenced by the reader and might be longer or shorter than those in the material at issue in this case where the first four images were displayed for approximately four seconds each before ending on the fifth image which was then static. The Panel considered that such cases should be considered individually in relation to the requirements of the Code.

Each image was of a tree showing its roots and with what appeared to be a couple and their dog underneath the tree. The first stated 'SPIOLTO – an advance in COPD care built on the strong roots of Spiriva (tiotropium)'. The second stated 'Superior lung function and less breathlessness vs Spiriva'. The third stated 'Superior quality of life vs Spiriva'. The fourth stated 'Respimat – designed for effective lung delivery' and included an image of the device firing. The final static image stated 'SPIOLTO – from the start of COPD mainenance therapy for better outcomes early on compared to Spiriva' and included an image of the closed device.

The Panel noted that Clause 4.3 required the non-proprietary name or the list of active ingredients using approved names where such existed to appear immediately adjacent to the most prominent display of the brand name. As the first banner included the non-proprietary name, tiotropium, immediately adjacent to the first mention of Spiriva the Panel ruled no breach of Clause 4.3.

The Panel noted that all five images included a clear, prominent statement as to where the prescribing information, adverse event reporting and references could be found. The Panel noted the complainant's allegation that the prescribing information was out of date. Boehringer Ingelheim submitted that the prescribing information was up-to-date. The Panel noted that it was for the complainant to prove his/her complaint on the balance of probabilities. No detail had been provided by the complainant as to why the prescribing information was not up-to-date. The Panel therefore ruled no breach of Clause 7.2 of the Code.

The Panel noted that from 14 February until 2 March the references had not been available via the link from the advertisement. The Panel noted that the case preparation manager had not raised Clause 7.6 with Boehringer Ingelheim. Clause 7.6 required that when promotional material referred to published studies clear references must be given. The Panel was therefore unable to make a ruling in that regard. Clauses 4.1 and 4.2 made no mention of the inclusion of references. Thus the Panel ruled no breach of Clause 4.1.

The Panel noted that the advertisement clearly promoted Spiolto Respimat and compared this with Spiriva. Spiriva was available as a Respimat and Handihaler. The Panel noted Boehringer Ingelheim's submission that the Spiolto clinical trials programme compared Spiolto and Spiriva Respimat and that Spiolto demonstrated statistically significant improvements in lung function, breathlessness and quality of life as stated in the advertisement. The Panel noted that these features appeared in the second and third images with the final image referring to 'Spiolto - From the start of COPD maintenance therapy for better outcomes early on compared to Spiriva'. The fourth banner stated 'Respimat – designed for effective lung delivery'. The Panel noted that although there was no specific mention of the Spiriva device used for the comparison, the fact that the studies used the same device (Respimat) for both medicines meant that readers would not be misled regarding the devices. The Panel thus ruled no breach of

Clause 7.2. The Panel considered that the claim for 'better outcomes' compared to Spiriva in the final image would be read in relation to the features compared in the advertisement and thus was not misleading. No breach of Clause 7.2 was ruled. The comparisons were substantiated by the material provided by Boehringer Ingelheim including the Spiolto SPC. The Panel thus ruled no breach of Clause 7.4.

The Panel noted its rulings above and did not consider that Boehringer Ingelheim had failed to maintain high standards. No breach of Clause 9.1 was ruled.

Complaint received **1 March 2017**

Case completed **15 May 2017**