CASE AUTH/3293/1/20

ANONYMOUS v BOEHRINGER INGELHEIM

Promotion of Pradaxa

An anonymous individual, who described him/herself as a health professional, complained about the promotion of Pradaxa (dabigatran) by Boehringer Ingelheim Limited. Pradaxa was an anticoagulant indicated for the prevention and treatment of certain thrombotic conditions.

The complainant alleged that the claim 'in any patient at increased risk of bleeding' could not be substantiated as the summary of product characteristics (SPC) stated that the medicine could not be used when renal function was severely impaired (CrCl <30mL/min) eg in elderly patients who were often initiated on Pradaxa. The complainant alleged a breach of the Code and referred to a risk to patient safety.

The complainant provided no details of the material in which the claim had been used nor of the context in which it had appeared.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that complainants had the burden of proving their complaints on the balance of probabilities. Complaints were judged on the evidence provided by the parties. The complainant had not referred to any promotional material or provided any details as to the context in which he/she had seen the claim at issue. As the complainant could not be contacted on the email address provided, further details from him/her could not be requested. The Panel noted, however, that Boehringer Ingelheim had provided a copy of the landing page to its website (ref PC-UK-101787 V1) which it stated was current when the complaint was submitted (30 December 2019) and so it was this material upon which the Panel based its rulings.

The Panel noted that the landing page for Boehringer Ingelheim's Pradaxa 110mg website included the claim 'Pradaxa 110 is the only low-dose [novel oral anticoagulant] for stroke prevention in atrial fibrillation recommended for use in any patient at increased risk of bleeding*'. Immediately below the claim in small font was the statement 'See how to select the right dose of Pradaxa' which appeared to be a link to further information. The asterisk took the reader to a footnote, in similarly small font which read 'Pradaxa 110 is also recommended for patients over 80 years of age and patients currently treated with verapamil'. The Panel considered that a busy health professional reading the website would assume that Pradaxa 110mg could be prescribed to all patients at increased risk of bleeding which was not so; it was contraindicated in those with severe renal impairment. That a link to further information had been provided was, in the Panel's view, irrelevant – it was an accepted principle under the Code that claims had to be capable of standing alone without recourse to footnotes and the like. The Panel noted, with concern, the reference to the over 80s in the footnote given that the risk of renal impairment increased

with age. The Panel considered that the claim was misleading, and a breach of the Code was ruled.

The Panel considered that Boehringer Ingelheim had failed to maintain high standards and a breach of the Code was ruled.

The Panel considered that there was a risk that some patients with severe renal impairment might be inappropriately treated with Pradaxa 110mg. The Panel considered that patient safety was of the utmost importance and that Boehringer Ingelheim's claim that Pradaxa 110mg could be used in any patient at increased risk of bleeding brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

An anonymous individual, who could not be contacted on the email address provided and who described him/herself as a health professional, complained about the promotion of Pradaxa (dabigatran) by Boehringer Ingelheim Limited. Pradaxa was an anticoagulant indicated for the prevention and treatment of certain thrombotic conditions.

COMPLAINT

The complainant alleged that the claim 'in any patient at increased risk of bleeding' could not be substantiated as the summary of product characteristics (SPC) stated that the medicine could not be used when renal function was severely impaired (CrCl <30mL/min) which could well be an elderly patient cohort who were often initiated on Pradaxa. The complainant alleged a breach of Clause 7.2 and referred to a risk to patient safety.

The complainant provided no details of the material in which the claim had been used nor of the context in which it had appeared.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clauses 2, 7.2 and 9.1.

RESPONSE

Boehringer Ingelheim stated that the phrase in question, '…in any patient at increased risk of bleeding', was used as part of a claim, however, the context in which it was used was key.

The phrase was part of a claim that health professionals could prescribe a lower dose (110mg) of Pradaxa at their discretion for patients at increased risk of bleeding in line with the SPC. The claim was included as part of a broader piece of content highlighting dose-reduction criteria, and was presented as 'Pradaxa 110mg [twice daily] may be prescribed in any patients at increased risk of bleeding', and was accompanied by the following supporting statement:

> 'Dose reduction should be considered based on your assessment of the patient's bleeding risk. Examples of increased bleeding risk may include: patients between 75-80 years; with moderate renal impairment (creatinine clearance 30-50ml/min); with gastritis, oesophagitis or gastroesophageal reflux. For further details of factors which may increase the bleeding risk, please refer to the Summary of Product Characteristics. Pradaxa is contraindicated in patients with severe renal impairment (creatinine clearance <30ml/min).'

Boehringer Ingelheim stated that, in conclusion, the claim in its entirety, was fully aligned with the SPC and met the requirements of Clause 7.2. Boehringer Ingelheim provided a copy of an on-line advertisement (ref PC-GB-100533) for use on a third-party website, which was the only piece of material which currently used the phrase in question.

It was noted that the on-line advertisement (ref PC-GB-100533 V1) provided by Boehringer Ingelheim in April was not approved until 27 February 2020 ie two months after the complaint was submitted and the company was notified. In response to a request from the case preparation manager for material which was current on 30 December 2019 (the date the complaint was submitted), Boehringer Ingelheim provided a copy of the landing page for its Pradaxa 110mg website (ref PC-UK-101787 V1) that was directed to from its third-party media advertisements. Boehringer Ingelheim noted that the material had subsequently been updated and no longer appeared in that form. With regard to the previously submitted material (ref PC-GB-100533 V1), Boehringer Ingelheim confirmed that the date of first use was 2 March 2020.

PANEL RULING

The Panel noted that complainants had the burden of proving their complaints on the balance of probabilities. Complaints were judged on the evidence provided by the parties. The complainant had not referred to any promotional material or provided any details as to the context in which he/she had seen the claim at issue. As the complainant could not be contacted on the email address provided, further details from him/her could not be requested. The Panel noted, however, that Boehringer Ingelheim had provided a copy of the landing page to its website (ref PC-UK-101787 V1) which it stated was current when the complaint was submitted (30 December 2019) and so it was this material upon which the Panel based its rulings.

The Panel noted that the landing page for Boehringer Ingelheim's Pradaxa 110mg website presented the medicine as having a high standard of evidence and, with over 6,000 patients in randomised clinical trials, a proven safety and efficacy profile. The website included the claim 'Pradaxa 110 is the only low-dose [novel oral anticoagulant] for stroke prevention in atrial fibrillation recommended for use in any patient at increased risk of bleeding*'. Immediately below the claim in small font was the statement 'See how to select the right dose of Pradaxa' which appeared to be a link to further information. The asterisk took the reader to a footnote, in similarly small font which read 'Pradaxa 110 is also recommended for patients over 80 years of age and patients currently treated with verapamil'. The Panel considered that a busy health professional reading the website would assume that Pradaxa 110mg could be prescribed to all patients at increased risk of bleeding which was not so; it was contraindicated in those with severe renal impairment. That a link to further information had been provided was, in the Panel's view, irrelevant – it was an accepted principle under the Code that claims had to be capable of standing alone without recourse to footnotes and the like. The Panel noted, with concern, the reference to the over 80s in the footnote given that the risk of renal impairment increased with age. The Panel considered that the claim was misleading, and a breach of Clause 7.2 was ruled.

The Panel considered that Boehringer Ingelheim had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel considered that there was a risk that some patients with severe renal impairment might be inappropriately treated with Pradaxa 110mg. The Panel considered that patient safety

was of the utmost importance and that Boehringer Ingelheim's claim that Pradaxa 110mg could be used in *any* patient at increased risk of bleeding brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **30 December 2019**

Case completed **18 December 2020**