NO BREACH OF THE CODE

CASE AUTH/3329/4/20

COMPLAINANT v BOEHRINGER INGELHEIM

Alleged promotion of Pradaxa to the public

A complainant, who described him/herself as a concerned UK health professional, complained about the on-line promotion of Pradaxa (dabigatran) by Boehringer Ingelheim. Pradaxa was an anti-thrombotic medicine indicated for use in the treatment or prevention of thrombotic events in adults including the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.

The complainant provided a screenshot of what looked like the opening page of the pradaxa.co.uk website which presented the reader with two boxes one aimed at UK health professionals and the other aimed at patients prescribed Pradaxa/members of the public where each of the intended audiences could click on a link for more information about the medicine. The complainant alleged that encouraging both members of the public and patients on treatment to use one of the boxes to seek more information about Pradaxa, constituted promotion to the public.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that the Code prohibited the advertising of prescription only medicines to the public. It permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. The supplementary information allowed for the provision of non-promotional information about prescription only medicines to the public as reference information made available by companies on their websites or otherwise as a resource for members of the public. It was considered good practice for such reference material to include, as a minimum, the SPC, the package leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document existed. Regulatory documents and reference material on the Internet made available to the public must not be presented in such a way as to be promotional in nature.

The Panel noted that the website in question was primarily aimed at health professionals and although members of the public might find it via an Internet search, they were not proactively directed to it or encouraged to access it. The Panel noted that the landing page clearly separated the link intended for health professionals from the link intended for patients prescribed Pradaxa/members of the public and according to Boehringer Ingelheim directed each to the information tailored for them. The Panel noted Boehringer Ingelheim's submission that the 'Information intended for: Patients Prescribed Pradaxa/Members of the Public' button redirected users through to non-promotional, factual reference information about Pradaxa that was suitable to be viewed by both

patients prescribed Pradaxa and members of the public. It included a short product overview of the medicine and its possible side effects and provided links to the Pradaxa patient information leaflets (ie the leaflets contained in the packs), the SPCs and patient alert card and the EPAR via links.

The Panel considered that the complainant had not discharged his/her burden of proof that the information provided on the website, and intended for both patients prescribed Pradaxa and members of the public, constituted promotion of Pradaxa to the public or that high standards had not been maintained and no breaches of the Code including Clause 2 were ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about the on-line promotion of Pradaxa (dabigatran) by Boehringer Ingelheim. Pradaxa was an anti-thrombotic medicine indicated for use in the treatment or prevention of thrombotic events in adults including the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.

COMPLAINT

The complainant provided a screenshot of what looked like the opening page of the pradaxa.co.uk website (ref PC-UK-100029 V1) which presented the reader with two boxes – a box on the left hand side of the screen was aimed at UK health professionals and the one on the right hand side was aimed at patients prescribed Pradaxa/members of the public. In both cases the intended audience could click on a link for more information about the medicine. The complainant alleged that encouraging both members of the public and patients on treatment to use the box on the right hand side to seek more information about Pradaxa, constituted promotion to the public.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 26.1.

RESPONSE

Boehringer Ingelheim explained that the webpage in question was the landing page of the Pradaxa.co.uk website. The website was a promotional website intended primarily for health professionals, but patients and members of the public might find it when searching the Internet. In order for the website to be open access, the company had provided a separate section with information for patients prescribed Pradaxa/members of the public to draw them away from the promotional area for health professionals. The page in question was to ensure that users who were not health professionals were provided with alternative non-promotional information as per the supplementary information to Clause 28.1.

Boehringer Ingelheim submitted that patients/members of the public would only access the page in question if they used search terms such as ‘Pradaxa’ or ‘dabigatran’, and then selected the product website from the results shown. There were no intervening pages shown prior to landing on the webpage in question when navigating from the search engine results page. The page in question provided access to the two clearly labelled sections, one for health professionals and one for patients/members of the public.

Boehringer Ingelheim noted that no outbound communications to patients/members of the public directing them to the website were sent, and therefore patients/members of the public were not encouraged to access the website.

Boehringer Ingelheim noted that the 'Information intended for: Patients Prescribed Pradaxa/Members of the Public' button redirected users through to the page 'Information relating to the use of Pradaxa in atrial fibrillation'. The information so provided was non-promotional, factual and limited to reference information, in compliance with Clauses 26.1, 26.2 and 28.5 of the Code, and the MHRA Blue Guide.

Boehringer Ingelheim submitted that the Pradaxa website aimed primarily to provide promotional information to health professionals but might be found by members of the public via an Internet search. In accordance with the requirements of Clause 28.1 and its supplementary information, the website also provided suitable alternative information for patients/members of the public, with the sections for each target audience clearly separated and labelled such that the intended audience was very clear. The Code made no separation between information permitted to be shared online with patients prescribed a medicine and other members of the public, as shown in Case AUTH/3184/4/19, where it was stated in the ruling that 'Publicly accessible information for patients should be suitable for the general public'. As such the information provided on the Pradaxa website did not differentiate between patient-only material and material for members of the public who were not patients.

The information provided on the patient and public section of the website was non-promotional, factual reference information about Pradaxa, in accordance with Clauses 26.2 and 28.5 of the Code, and the MHRA Blue Guide 2019, and was suitable to be viewed by both patients prescribed Pradaxa and members of the public. It included a short product overview and access to the Pradaxa patient information leaflets, summaries of product characteristics (SPCs) and patient alert card via a link to the electronic medicines compendium (eMC), and to the European Public Assessment Report (EPAR) via a link to the European Medicines Agency (EMA) website.

As the primary route of access to these pages by patients/members of the public would be from searches specifically for the product, there were no proactive communications of the site to those who were not health professionals, and as the company had clearly sign-posted patients/members of the public to areas of information relevant to them, and clearly away from areas on the website intended only for health professionals, Boehringer Ingelheim considered that it had complied with the requirements of Clauses 26.1.

For the reasons stated above, plus the robust compliance and training programmes implemented within the company, Boehringer Ingelheim denied a breach of Clause 26.1 and considered that it had upheld high standards by ensuring that members of the public were not inadvertently exposed to any Pradaxa promotional material on the website. The company thus also denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The complainant noted that the highlighted box on the right hand side of the landing page of the Pradaxa website was aimed at both patients who had been

prescribed the medicine and members of the public who wanted to access information about Pradaxa and alleged that therefore it promoted Pradaxa to the public.

The Panel noted that the supplementary information to Clause 28.1 stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to.

The Panel further noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public. Clause 26.2 permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. The supplementary information stated that Clause 26.2 allowed for the provision of non-promotional information about prescription only medicines to the public as reference information made available by companies on their websites or otherwise as a resource for members of the public. It was considered good practice for such reference material to include, as a minimum, the SPC, the package leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document existed. Clause 28.5 similarly allowed for the provision of regulatory documents and reference material on the Internet to be accessible by members of the public provided that they were not presented in such a way as to be promotional in nature.

The Panel noted that the website in question was primarily aimed at health professionals and although members of the public might find it via an Internet search, they were not proactively directed to it or encouraged to access it. The Panel noted that the landing page of the Pradaxa website clearly separated the link intended for health professionals from the link intended for patients prescribed Pradaxa/members of the public (should they find it via an Internet search) and according to Boehringer Ingelheim directed each to the information tailored for them. The Panel noted Boehringer Ingelheim's submission that the 'Information intended for: Patients Prescribed Pradaxa/Members of the Public' button redirected users through to non-promotional, factual reference information about Pradaxa that was suitable to be viewed by both patients prescribed Pradaxa and members of the public. It included a short product overview of the medicine and its possible side effects and provided links to the Pradaxa patient information leaflets (ie the leaflets contained in the packs), the SPCs and patient alert card via a link to the eMC, and to the EPAR via a link to the EMA website.

The Panel considered that the complainant had not discharged his/her burden of proof that the information provided on the website, and intended for both patients prescribed Pradaxa and members of the public, constituted promotion of Pradaxa to the public and no breach of Clause 26.1 was ruled.

The Panel noted its comments above and considered that there was no evidence that high standards had not been maintained. No breach of Clause 9.1 was ruled. The Panel consequently also ruled no breach of Clause 2.

Complaint received **14 April 2020**

Case completed **1 July 2020**