CASE AUTH/3270/10/19

COMPLAINANT v BAYER

Xarelto website

A complainant who described him/herself as a concerned UK health professional, complained about Bayer's website for Xarelto (rivaroxaban). Xarelto was a prescription only medicine indicated to prevent or treat certain acute circulatory conditions in adults.

The complainant noted that the homepage of the website had significant mention of Xarelto. There were two 'boxes' on which to click for more information – one for health professionals and one for patients and the public. The information provided for patients and the public was not on the disease, but more information on the product; they could click a link to the Xarelto summary of product characteristics (SPC) and the patient information leaflet (PIL) and were invited to contact medical information for more information about the medicine.

The complainant alleged that Xarelto had been promoted to the public and that patients and the public had been encouraged to contact medical information specifically about the medicine which should be for health professionals only – unless medical information was to be used to encourage patients to see their physicians to discuss the product.

The detailed response from Bayer is given below.

The Panel noted that according to Bayer the purpose of the website was to host reference information on Xarelto for UK health professionals, patients and members of the public. Bayer submitted that the information provided for patients or the public comprised general information about atrial fibrillation and venous thromboembolism with links to relevant guidance and patient organisations/charities for each condition as well as to the Xarelto SPC and PIL. The Panel did not consider that the complainant had discharged his/her burden of proof that the information provided on the patients and public section of the website promoted Xarelto to members of the public or would encourage them to ask their health professional to prescribe it. No breaches of the Code were ruled.

The Panel noted that there were no claims for Xarelto on the landing page nor were the indications listed. With regard to 'significant mention' of Xarelto on the landing page, the Panel noted that the product name was cited three times – once in logo format in the top left hand corner and once in normal font in each of the boxes which health professionals or patients/public could click for more information. The Panel did not consider that the complainant had discharged his/her burden of proof that references to Xarelto on the landing page promoted Xarelto to members of the public or would encourage them to ask their health professional to prescribe Xarelto. No breaches of the Code were ruled.

As required, the sections of information for health professionals and for patients/public were clearly separated and the intended audiences identified. The Panel ruled no breach of the Code.

The Panel noted that a statement at the bottom of the patient/public webpage read, 'For more information on Xarelto, please contact [email address for medical information at Bayer]'. In that regard, the Panel disagreed with Bayer's submission that the statement was not to encourage contact with medical information, but simply to provide the contact details of the medical information service available. The Panel noted that supplementary information to the Code allowed, within limits, non-promotional information about prescription only medicines to be provided to the public. A company could provide proactive information and/or it could provide reference information on its website; it could also provide reactive information in response to a direct request as long as it was limited to that information necessary to respond to the request. In the Panel's view the latter referred to an unsolicited request. The Panel considered that those who sought out a website were likely to want to access as much information as possible. Whilst providing general contact details on a website was good practice, the Panel considered that by inviting members of the public to contact the company for more information about Xarelto, Bayer had solicited requests about a prescription only medicine and had thus gone beyond the provision of reference information and reactive information in response to a direct, unsolicited request allowed under the Code. The Panel considered that high standards had not been maintained and a breach of the Code was ruled.

The Panel did not know what sort of information, if any, had been provided as a result of someone contacting the company via the website. The Panel did not consider that there was evidence that the invitation to contact medical information had, in and of itself, promoted Xarelto to members of the public or encouraged them to ask their health professional to prescribe it as alleged. Nor was there any information to show that once contacted, medical information had promoted Xarelto to members of the public or encouraged them to ask their health professional to prescribe it as alleged. No breaches of the Code were ruled.

The Panel noted that a ruling of a breach of Cause 2 was a sign of particular censure and reserved for such. The Panel noted its comments and rulings above but did not consider, in the particular circumstances of this case, that a ruling of a breach of Clause 2 was warranted. No breach was ruled.

A complainant who described him/herself as a concerned UK health professional, complained about Bayer's website for Xarelto (rivaroxaban). Xarelto was indicated to prevent or treat certain acute circulatory conditions in adults.

COMPLAINT

The complainant noted that the homepage of the website had significant mention of Xarelto. There were two 'boxes' on which to click for more information – one for UK health professionals and one for patients and the public. The complainant noted that patients and the public shared one box and were taken to the same place – not for more information on the disease, but more information on the product. At the base of the page for patients/public readers could click a link to the Xarelto summary of product characteristics (SPC) and the patient information leaflet.

They were also invited to contact medical information if they wanted more information about the medicine.

The complainant alleged that Xarelto had been promoted to the public and that patients and the public had been encouraged to contact medical information specifically about the medicine which should be for health professionals only – unless medical information was to be used to encourage patients to see their physicians to discuss the product.

When writing to Bayer, the Authority asked it to consider the requirements of Clauses 2, 9.1, 26.1, 26.2 and 28.1.

RESPONSE

Bayer explained that the objective of the website was to host reference information on Xarelto for UK health professionals, patients and members of the public in accordance with the Code.

The landing page, as referred to by the complainant was comprised of a header with two website division tabs in the middle of the page, according to the appropriate target audience 'UK Healthcare Professionals' and 'Patients and Public', and a landing page footer.

'Xarelto' appeared three times on the landing page:

1 The header on the top left contained the brand and generic name with a black triangle indicating the reader was on the Xarelto-info.co.uk website:
2 The 'For UK Healthcare Professionals' section read, 'If you are a UK healthcare professional and would like more information on Xarelto (rivaroxaban) please click here'.
3 The 'For Patients and Public' section reads, 'For more information on Xarelto please click here'.

While the product name was used three times, due to the target audience being diverted to the relevant section, it would typically be read just twice by the relevant reader. Bayer did not consider that this amounted to a significant mention of the product as asserted by the complainant or that the landing page would promote Xarelto to the public contrary the Code. Nor did the company consider that the landing page would encourage members of the public to request Xarelto from their health professional contrary to the Code.

Bayer noted that, as required by Clause 28.1, it had provided separate sections for health professionals and members of the public.

The objective for the patient and public section of the website was to host reference information on Xarelto such as the summary of product characteristics (SPC) and patient information leaflet (PIL), as well as to provide disease information.

When a patient or member of the public clicked on the 'For Patients and Public' tab from the landing page, they were prompted by a message to confirm they were a patient or member of the public. Once on the 'For Patients and Public' webpage, a disclaimer appeared in larger font:

> 'This section contains **reference information only**, is general in nature and intended to provide a general overview of atrial fibrillation and venous thromboembolism for the UK

general public. It is not intended to replace in any way the opinion of a healthcare professional.'

The disclaimer was followed by two disease information tabs: atrial fibrillation and venous thromboembolism and a list of external links to National Institute for Health and Care Excellence (NICE) guidance and relevant patient organisation and patient charity websites.

Above the footer on the 'For Patients and Public' webpage, there was a statement which provided links to non-promotional regulatory documents: the SPC and PIL. Bayer noted that the supplementary information to Clause 26.2 stated that it was considered good practice to provide such reference information.

The information in this section was reference and disease information. As such, Bayer did not consider that the website promoted Xarelto to the public, nor did it encourage a member of the public to ask his/her health professional to prescribe the product contrary to Clauses 26.1 and 26.2 of the Code respectively. Bayer also denied a breach of Clause 28.1, the supplementary information to which required separate sections for health professionals and member of the public.

Bayer submitted that the provision of information to members of the public from a medical information service was specifically referenced in the supplementary information to Clauses 26.2, 'Approval of Information' and 26.4, 'Request for Information or Advice on Personal Medical Matters'. Therefore, it did not agree that the medical information service was for health professionals only.

Bayer stated that the statement highlighted by the complainant was not to encourage contact with medical information, but simply to provide the contact details of the service available. The medical information service always complied with Clauses 26.2 and 26.4 of the Code, including the supplementary information.

In conclusion, Bayer reiterated that the objective of the website was to host reference information on Xarelto for UK health professionals, patients and member of the public. The website was not pushed or promoted to members of the public but existed in the digital space, as a source of reference information. Bayer considered that the website was in accordance with Clauses 26.1, 26.2 and 28.1 including the associated supplementary information. The company denied breaches of Clause 9.1 or 2.

PANEL RULING

The Panel noted that Clause 28.1 stated that promotional material about prescription only medicines directed to a UK audience, provided on the Internet, must comply with all the relevant requirements of the Code. 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 according to Bayer the purpose of the website in question was to host reference information on Xarelto for UK health professionals, patients and members of the public. The Panel noted Bayer's submission that the information provided for patients or the public comprised general information about atrial fibrillation and venous thromboembolism with links to relevant guidance and patient organisations/charities for each condition as well as to the Xarelto SPC and PIL. The Panel did not consider that the complainant had discharged his/her burden of proof that the information provided on the patients and public section of the website, promoted Xarelto to members of the public or would encourage them to ask their health professional to prescribe Xarelto. No breach of Clauses 26.1 and 26.2 was ruled.

The Panel noted that there were no claims made for Xarelto on the landing page nor were the indications listed. With regard to the complainant's reference to 'significant mention' of Xarelto on the landing page, the Panel noted that the product name was cited three times – once in logo format in the top left hand corner and once in normal font in each of the boxes which health professionals or patients/public could click for more information. The Panel did not consider that the complainant had discharged his/her burden of proof that references to Xarelto on the landing page promoted Xarelto to members of the public or would encourage them to ask their health professional to prescribe Xarelto. No breach of Clauses 26.1 and 26.2 was ruled.

Further, as required by the supplementary information to Clause 28.1, the sections of information for health professionals and for patients/public were clearly separated and the intended audiences identified. The Panel ruled no breach of Clause 28.1.

The Panel noted Bayer's submission that the provision of information by medical information to members of the public was referred to in the supplementary information to Clauses 26.2, Approval of Information and 26.4, Request for Information or Advice on Personal Medical Matters. The Panel noted, however, that the supplementary information to Clause 26.2 specifically referred to unsolicited enquiries, an enquiry made without any prompting from the company, from the public and that Clause 26.4 specifically referred to advice on personal medical matters. In the Panel's view, the patient/public section of the website, with its implicit invitation to contact medical information about Xarelto, solicited enquiries about the medicine from patients/public and thus the supplementary information relied upon by Bayer was not relevant to the matter in question.

Although the Panel noted that while the patient information leaflet (not provided by Bayer but viewed on the Electronic Medicines Compendium (eMC) website) stated 'For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: United Kingdom, Bayer plc, [telephone number provided]' that invitation to contact the

company was offered to those who had already been prescribed the medicine, not to the general public.

The Panel noted that a statement at the bottom of the patient/public webpage read, 'For more information on Xarelto, please contact [email address for medical information at Bayer]'. In that regard, the Panel disagreed with Bayer's submission that the statement was not to encourage contact with medical information, but simply to provide the contact details of the medical information service available. The Panel further noted that the statement appeared to be more prominent on the patient/public webpage than it was on the health professional webpage. The Panel noted that the supplementary information to Clause 26.2 stated that the clause allowed for the provision of non-promotional information about prescription only medicines to the public via three categories depending on its purpose, how it was supplied and how the public was made aware of the information. The categories included (1) proactive information which was supplied to the public without a direct request and included booklets on diseases and/or medicines supplied directly or via a health professional, press releases, briefings, conferences, mailings to patient organisations and disease awareness advertising; (2) reference information which was intended to provide a comprehensive up-to-date resource that companies should make available on their websites or by way of a link from their website or by some other means; and (3) reactive information which was supplied to the public in response to a direct request and must be limited to that information necessary to respond to the request which, in the Panel's view, referred to an unsolicited request. The Panel considered that those who took the trouble to seek out a website were likely to want to access as much information as possible. The Panel noted that whilst providing general contact details on a website was good practice, it considered that by inviting members of the public to contact the company for more information about Xarelto, Bayer had solicited requests about a prescription only medicine and had thus gone beyond the provision of reference information and reactive information in response to a direct, unsolicited request allowed under Clause 26.2 as referred to in the supplementary information to that clause. The Panel considered that Bayer had failed to maintain high standards in that regard and a breach of Clause 9.1 was ruled.

The Panel did not know what sort of information, if any, had been provided as a result of a member of the public contacting the company via the contact details provided on the website. On the information before it, the Panel did not consider that there was evidence that the invitation to contact medical information at Bayer for more information on Xarelto had, in and of itself, promoted Xarelto to members of the public or encouraged them to ask their health professional to prescribe it as alleged. Nor was there any information to show that once contacted, medical information had promoted Xarelto to members of the public or encouraged them to ask their health professional to prescribe it as alleged. No breach of Clauses 26.1 and 26.2 were ruled.

The Panel noted that a ruling of a breach of Cause 2 was a sign of particular censure and reserved for such. The Panel noted its comments and rulings above but did not consider, in the particular circumstances of this case, that a ruling of a breach of Clause 2 was warranted. No breach was ruled.

Complaint received **25 October 2019**

Case completed **5 August 2020**