CASE AUTH/3873/1/24 ***NO BREACH OF THE CODE***

COMPLAINANT v BAYER

Allegations about information on a Bayer website

CASE SUMMARY

This case was in relation to a patient discussing their treatment with a health professional and showing them a printout of the Summary of Product Characteristics (SPC) for Eylea. The complainant described themselves as the health professional for that patient. The patient had allegedly explained that they had been able to access the SPC through a Bayer-owned website for Eylea. Part of the allegation was that this material should have been accessible only to health professionals.

The outcome under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe specific prescription only medicine**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about Bayer plc was received from an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Hello. I was asked today by a patient some confused particulars about their treatment, and when asked where they had been told some of it, they showed me a print out of an smpc for Eylea injectables. I explained this was intended for professionals, and they insisted they had googled the drug and had been directed to it by the website they had found and was for patients. Indeed, on the [link provided] website, selecting the patient option takes you to a page prominently directing me to the smpc, which then clearly states it is for use by healthcare professionals only."

When writing to Bayer, the PMCPA asked it to consider the requirements of Clauses 5.1 and 26.2 of the 2021 Code.

BAYER'S RESPONSE

The response from Bayer is reproduced below:

> "Thank you for your letter dated 26 January 2024, in which you notify us of a complaint to the PMCPA ('Complaint') from an anonymous complainant who describes him/herself as a health professional ('Complainant'). Bayer has been asked to consider Clauses 5.1 and 26.2 of the 2021 UK APBI Code of Practice ('the Code') in relation to its response.
>
> Bayer takes its responsibility to comply with the Code and to maintain high standards extremely seriously. We welcome the opportunity to respond to this complaint and provide a full rebuttal to the satisfaction of the Panel. Bayer does not accept that the website in question breaches Clause 5.1 and 26.2 of the Code.
>
> **Complaint**
>
> The Complainant states the following: [complaint wording reproduced].
>
> It is not made explicit in the wording of the complaint but we assume from the above that the complainant is objecting to their patient being able to access the Eylea Summary of Product Characteristics (SmPC) via the patient portal of the [link provided] website because the SmPC is a document intended for health professionals and is marked as such on the hosting webpage [link provided]. Our response to the complaint is based upon this interpretation.
>
> **Further questions from PMCPA**
>
> In the letter of 26 January, the PMCPA asks two specific questions in relation to the eylea.co.uk site:
>
> - Whether the material could be accessed directly from a googlesearch without any restrictions, as alleged by the complainant
> - Any arrangements Bayer has in place to satisfy itself that the webpage is accessed by an appropriate audience
>
> We have answered these additional questions below.
>
> **Structure of and access to Eylea.co.uk website**
>
> Bayer confirms that the website referred to in the complaint is a current Bayer UK website for Eylea (aflibercept): [link provided]. The Complainant does not provide details of when they or their patient accessed the site, but the complaint was submitted to the PMCPA on 24 January 2024 so we must assume the date(s) of access must be on or before this date. It is therefore important to make the Panel aware that the eylea.co.uk website received a major update on 30 January 2024, 4 days after the complaint was received by Bayer. This update was made following receipt of a

marketing authorisation for a new 8mg (114.3 mg/mL aflibercept) dose of Eylea on 19 January 2024, in addition to the original 2mg (40 mg/mL) dose, as it was necessary to include material for both doses on the site. Work on preparing this update had begun before we received the complaint.

Many of the pages in the current website have therefore changed considerably from those accessed by the PMCPA following receipt of the complaint on 24 January and your letter to Bayer on 26 January. In responding to the complaint, we have provided certificates for the website screenshots provided by the PMCPA as attachments to the letter of 26 January (i.e. the website as it would have been accessed by the Complainant and their patient) and not the current certificates for the site as it now appears. We are of course more than happy to provide any further information required by the PMCPA.

The Complainant states that the website was found by their patient as part of a general internet search and there is (correctly) no suggestion in the complaint that the patient was proactively directed to the site nor encouraged to access it by Bayer. Details of the search terms used by the patient were not provided by the Complainant. Our assumption is therefore that the patient searched for 'Eylea' and chose to access the eylea.co.uk site from amongst the search results generated.

In line with the requirements of Clause 26.2 of the Code (supplementary information to clause 26.2, website access), this website provides separate areas for UK health professionals (containing promotional content) and members of the UK general public (containing only non-promotional content). The two areas are separated by an 'honesty box' gateway ensuring that members of the public are directed away from the promotional site and have access to appropriate non-promotional reference material on Eylea. This principle for structuring product websites has also been accepted by the PMCPA in several previous Code cases, for example AUTH/3329/3/20. There is no absolute restriction preventing an individual entering any part of the site (for example, there is no password-controlled entry), but the Code does not demand this. The arrangements in place meet the requirements of Clause 26.2 and the recommendations in the associated supplementary information.

As the Complainant states, a link is provided within the patient section of the eylea.co.uk website leading to a third-party website (Electronics Medicines Compendium (eMC)) [link provided] where all Eylea SmPCs are hosted. Access to the Eylea SmPCs is provided on eylea.co.uk via eMC linkage to ensure the most current version of the SmPC is always used. Members of the public clicking on the link to the eMC site from eylea.co.uk are informed that they are now leaving the eylea.co.uk website, that the content of the website they are visiting is not controlled by the eylea.co.uk team and the link is being offered for their convenience and should not be viewed as an endorsement of the content, product or services offered. They have to click 'OK' to leave the Bayer-controlled site.

Bayer is therefore satisfied that the design of the website is such as to comply with the Code and to ensure the relevant parts of it are accessed by the appropriate audience.

Suitability of SmPCs for general public use as reference material on prescription-only medicines

The eMC website marks all SmPCs with the prominent statement *'This information is for use by healthcare professionals'.* The Complainant appears to be referring to this in the complaint.

Bayer does not dispute that SmPCs are regulatory documents intended primarily for use by health professionals. However, it is stated in the supplementary information to Clause 26.2 of the Code that *'it is considered good practice'* for pharmaceutical companies to provide reference information on their websites as a library resource for members of the public relating to prescription only medicines which have marketing authorisations. As part of further defining good practice in relation to resources for the public, the supplementary information to Clause 26.2 goes on to recommend the SmPC as one of the regulatory documents which can be included as a minimum requirement to meet the need for public reference material. In addition, Clause 1.17 of the Code specifically excludes SmPCs from the definition of promotion.

Please note that the Eylea patient information leaflet has always been provided as another reference option for members of the public on eylea.co.uk (again, via a link to the eMC), alongside links to the SmPC.

It is therefore the view of Bayer that provision of the SmPC as non-promotional reference material for the public is not only compliant with the requirements of the Code but is recommended by the PMCPA and considered good practice in this regard.

Summary

Bayer affirms that the links to the Eylea SmPC provided in the public section of the eylea.co.uk site are intended to meet the recommendations of Clause 26.2 in relation to reference information intended to provide members of public with a comprehensive, up-to-date non-promotional resource on Eylea. As stated in the supplementary information to Clause 26.2, provision of the SmPC as part of non-promotional reference material for prescription-only medicines is both recommended and considered good practice by the Code.

Bayer therefore denies a breach of Clause 26.2.

The structure of the eylea.co.uk website was designed with the requirements and recommendations of Clause 26.2 in mind, as well as previous PMCPA Panel rulings relating to the Code in relation to general public access to websites concerning prescription-only medicines. Bayer is confident that this website is appropriately gated such that members of the public can clearly identify and access appropriate non-promotional reference material on Eylea, of which the SmPC is an example. The intended audience for each part of the site is clearly defined.

All the relevant Bayer webpages have been appropriately certified by a medical signatory. The Bayer signatories involved in certifying this material are listed below as requested; both are appropriately qualified and registered appropriately with the MHRA and PMCPA:

- [Named ophthalmology doctor],
- [Named medical advisor]

Certificates for the sections of the website provided as attachments to your letter are enclosed as annexures, along with the Great Britain SmPC for Eylea 40mg/mL (2mg dose) in a pre-filled syringe.

Bayer affirms that it has maintained high standards at all times in relation to eylea.co.uk, and has made every effort to align with recommended good practice in this area as defined by the Code.

Bayer therefore denies a breach of Clause 5.1.

Bayer PLC is committed to upholding the requirements of the ABPI Code of Practice. We hope our response addresses your concerns accordingly and look forward to your response in due course."

PANEL RULING

This complaint concerned a patient discussing their treatment with a health professional and showing them a printout of the Summary of Product Characteristics (SPC) for Eylea. The complainant described themselves as the health professional for that patient. The patient had allegedly explained that they had been able to access the SPC through a Bayer-owned website for Eylea. Part of the allegation was that this material should have been accessible only to health professionals.

Clause 26.2

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 (SI) to that clause (in the "*Information to the Public*" section) stated that it "*allows for the provision of non-promotional information about prescription only medicines to the public*", which "*includes reference information made available by companies on their websites or otherwise as a resource for members of the public*". The SI also provided (in the "*Reference Information*" section) that "*it is considered good practice to provide as a minimum the regulatory information comprising the summary of product characteristics*".

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The patient claimed to have conducted a Google search for Eylea and been able to access the Eylea website from the search options.

The Panel noted Bayer's submission that, when clicking on the website link, the user would be immediately presented with an 'honesty gateway' box asking whether they were a UK health professional or a member of the public. The 'For members of the public' link would then redirect users through to non-promotional reference material on Eylea, whereas the 'For UK healthcare professionals' link provided promotional content. The public section of the Eylea website contained links to the patient information leaflet and the SPC via the Electronics Medicines Compendium (EMC) website.

The Panel accepted that the landing page clearly separated the content intended for health professionals from the content intended for patients or members of the public and required users to click on which one applied. The Panel considered the SI to Clause 26.2 to be relevant in this case given that it stated that:

(a) a pharmaceutical company website providing information to the public as well as promotion to health professionals must have sections for each target audience clearly separated ("*Website Access*" section of the SI), and
(b) it is considered good practice to provide regulatory information such as the SPC on a non-promotional website intended for patients or members of the public ("*Reference Information*" section of the SI).

The Panel considered that Bayer had satisfied those requirements in the context of this case. The Panel therefore concluded that the complainant had not established that the provision of the Eylea SPC via a link on the patient webpages of the Eylea website was inappropriate as alleged and therefore ruled **no breach of Clause 26.2**.

Clause 5.1

Given its ruling in relation to Clause 26.2, the Panel considered that there was no additional evidence that high standards had not been maintained in this case. **No breach of Clause 5.1** was ruled.

Complaint received **24 January 2024**

Case completed **6 January 2025**