CASE AUTH/3684/8/22

COMPLAINANT v BAYER

Promotion of Kerendia on MailOnline

CASE SUMMARY

This case was in relation to an advertisement for Kerendia (finerenone) published by Bayer on a UK news website. The Panel considered that the banner advertisement, with multiple prominent mentions of the brand name of the prescription only medicine Kerendia, and the link to a Kerendia US website, which was product-related, could not be considered as anything other than Kerendia promotional material.

The Panel ruled a breach of the following Clauses of the 2021 Code on the basis that the promotional banner advertisement did not satisfy the Code requirements for promotional material and was accessible to members of the public:

Breach of Clauses 3.2 and 26.1	**Advertising a prescription only medicine to the public (Panel made one ruling which applied to both Clauses)**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 8.1	**Failing to certify promotional material**
Breach of Clause 12.1	**Failing to include UK prescribing information**
Breach of Clause 12.9	**Failing to include an adverse event reporting statement**
Breach of Clause 16.1	**Producing promotional material about prescription only medicines directed to a UK audience, provided on the internet, which did not comply with all the relevant requirements of the Code**
Breach of Clause 26.2	**Encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine**

The Panel ruled no breach of the following Clauses of the 2021 Code because:

- **The expanded version of the fourth frame of the banner advertisement stated the date of preparation of the material**
- **The Panel did not consider that the banner advertisement at issue was an abbreviated advertisement**
- **On the narrow technical point that the banner advertisement was considered to be promotional material, it did not fail to meet the requirement that any material related to a medicine intended for patients taking that medicine must include a reporting of side effects statement**
- **The linked website to the banner advertisement was clearly intended for a US audience; the complainant had limited their reason for an alleged breach of**

Clause 2 to the overall number of breaches; the Panel considered, on balance, that its breach of Clause 5.1 adequately covered the matter

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 12.8	**Requirement that promotional material must include the date on which the promotional material was created or last revised**
No Breach of Clause 13.2	**Requirement that abbreviated advertisements may only appear in professional publications**
No Breach of Clause 13.6	**Requirement that abbreviated advertisements must include the prominent adverse event reporting statement**
No Breach of Clause 26.4	**Requirement that any material which relates to a medicine and which is intended for patients taking that medicine must include a reporting of side effects statement**

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 was received from a contactable complainant who described themselves as an employee in a healthcare communications agency about an advertisement for Kerendia (finerenone) published by Bayer.

COMPLAINT

The complainant alleged that Bayer advertised a chronic kidney disease (CKD)/diabetes prescription only medicine on a UK website. While the advertisement was made for a US public audience and redirected to a US website, it was displayed on a MailOnline article, with a '.co.uk' URL and written by a UK journalist. The complainant alleged that this was a massive failure from a digital targeting point of view, which could have been avoided, and placed Bayer in breach of Clauses 3.2 and 26.1 ('Prescription only medicines must not be advertised to the public') and Clause 26.2 ('Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine').

Because it was impossible to scroll down the advertisement to read more (despite the advertisement displaying a scroll bar), the complainant alleged that Bayer had breached the following Clauses of the Code: Clause 12.1 (displaying prescribing information), Clause 12.8 (date of preparation), Clause 8 (UK certification), Clauses 12.9, 13.6, and 26.4 (instructions to report adverse events) and Clause 16.1 ('Promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code') .

As it was in a public outlet, the complainant submitted that Bayer had breached Clause 13.2 ('Abbreviated advertisements may only appear in professional publications …').

The complainant alleged that because of the sheer amount of breaches (11 so far), they believed this was also a breach of Clause 2 (upholding confidence in the industry) and Clause 5 (maintaining high standards and suitability).

The complainant provided a screen recording of the advertisement in question.

When writing to Bayer, the Authority asked it to consider the requirements of Clauses 2, 3.2, 5, 8, 12.1, 12.8, 12.9, 13.2, 13.6, 16.1, 26.1, 26.2 and 26.4 of the 2021 Code as cited by the complainant.

RESPONSE

Bayer submitted that the complaint was in relation to the promotion of Kerendia, which was a prescription only medicine, via a direct-to-consumer (DTC) banner advertisement which appeared next to a MailOnline article written by a UK medical journalist (about a medical condition unrelated to the therapeutic indication for Kerendia) on Saturday, 6 August 2022.

The complainant noted that the advertisement was intended for the US public and was linked to a US website for Kerendia. The complainant provided a screen recording of both the MailOnline article, alongside which the DTC banner advertisement was displayed, and of the US Kerendia website, which could be accessed via the banner advertisement.

The complainant alleged breaches of the following Clauses of the 2021 Code: 2, 3.2, 5, 8, 12.1, 12.8, 12.9, 13.2, 13.6, 16.1, 26.1, 26.2 and 26.4.

Background

Bayer submitted that a US-originated Kerendia DTC National Digital Campaign (the Campaign) posted by Bayer LLC ('Bayer US'), and intended solely for availability and access in the US, was inadvertently accessible in the UK. The Campaign was live between 1 July to 16 August 2022 and contained a link to the Kerendia US consumer website. The website was intended only for US residents and this was stated on the landing page of the website.

Internal investigation into how the Campaign came to be accessible in the UK

Bayer submitted that its investigation determined that the geo-location settings for the advertisement were not restricted to US only. This error occurred because advertisement space-buying software, which had been implemented by Bayer LLC over the last 18 months, did not default to US only. The step in the process where the target geography was determined was subject to operator decision but in this case, was overlooked and consequently defaulted to a distribution outside the US, including the UK.

The US team had confirmed that no other DTC campaigns ran to date using the new advertisement-buying software were launched without the US only geo-restriction.

Actions taken as a result of the complaint

The Campaign was stopped immediately on 16 August 2022, the same date as the PMCPA's letter to Bayer plc, after Bayer US was alerted to the issue by Bayer plc colleagues. The error in

geo-location settings was corrected as soon as Bayer US became aware of the issue and Bayer US confirmed that the Campaign was, thereafter, limited to US-only geography.

Internal procedures had been put in place to ensure that future Bayer US digital DTC campaigns would, by default, be limited to US-only geography. The Bayer US advertisement buying platform now had a default setting for US-only geography; and the Quality Assurance 'Go/No-Go' checklist had been updated to include confirmation of the US-only geography limitation.

Bayer's response to the clauses cited as being breached

Bayer plc submitted that it accepted the allegations of, and sincerely apologised for, breaches of Clauses 3.2, 5, 8, 16.1 and 26.2 consequent to the US Kerendia DTC advertising campaign being inadvertently accessible in the UK. Bayer submitted that it also accepted that it was in breach of Clause 2 due to the seriousness of the error. Bayer plc considered that there should be clarification with respect to the alleged breaches of Clauses 5 and 8, and that Clauses 12.1, 12.8, 12.9, 13.2, 13.6, 26.1 and 26.4 had not been breached. Bayer plc provided the reasoning below:

- The complainant alleged there had been a breach of Clause 5 and referred to 'maintaining high standards and suitability' – these latter words being in brackets after Clause 5 had been cited by the complainant. Bayer plc considered that the relevant clause was more specifically Clause 5.1 which was that 'High standards must be maintained at all times'. Bayer accepted that a breach of Clause 5.1 had occurred. With respect to Clauses 5.2 to 5.7, Bayer considered that these were not specifically applicable to this complaint.

- The complainant alleged there had been a breach of Clause 8 and referred to 'UK certification' – these latter words being in brackets after Clause 8 had been cited by the complainant. Bayer plc considered that the relevant clause was more specifically Clause 8.1 which was that 'Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause …'. Bayer accepted that a breach of Clause 8.1 had occurred. With respect to Clauses 8.2 to 8.6, Bayer considered that these were not specifically applicable to this complaint.

- Bayer plc did not consider the US Kerendia digital banner advertisement was subject to Clauses 13.2 and 13.6 as these clauses applied specifically to abbreviated advertisements. Bayer, therefore, believed that these clauses had not been breached.

- Clauses 3.2 and 26.1 had identical wording relating to 'Prescription only medicines must not be advertised to the public'. Bayer believed that being ruled in breach of Clause 3.2 precluded also being ruled in breach of Clause 26.1.

- The criteria for a breach of Clause 12.8 had not been met (date of preparation was not included in the banner advertisement). Bayer plc had identified the original Bayer US documentation which displayed both the reference number and date of preparation, namely March 2022.

- Breaches of Clauses 12.1 and 12.9 about the provision of prescribing information (PI) and the inclusion of a health professional adverse event (AE) reporting statement, respectively, should not be ruled because Clauses 11-17 of the Code applied specifically to 'Promotion to Health Professionals and Other Relevant Decision Makers' whereas the US Kerendia DTC was a banner advertisement aimed, admittedly in this case inadvertently, at consumers/patients and not an advertisement aimed at health professionals.

- A breach of Clause 26.4 should not be ruled because this referred to the need to include a statement about 'Reporting of side effects' in any material which related to a medicine and which was intended for patients taking that medicine. The US Kerendia DTC was a banner advertisement and not intended for patients who were already taking the medicine Kerendia.

Conclusion

Bayer submitted that human error within Bayer US during the set-up of a US Kerendia DTC – whereby geo-location settings were not restricted to the US – inadvertently resulted in the Campaign being accessible in the UK. The Campaign appeared as a banner advertisement in the MailOnline and it was possible to click through to the Kerendia US consumer website.

Bayer plc was extremely disappointed that there was human error by a colleague or colleagues in Bayer US which resulted in the banner advertisement being accessible and visible in the UK. To the best of Bayer's knowledge this had not occurred previously and robust measures had now been implemented to ensure that this did not happen again.

The campaign was stopped immediately on the same date as the PMCPA letter to Bayer UK about the complaint. The error in geo-location settings was corrected as soon as Bayer US became aware of the issue and confirmed that the Campaign was, thereafter, limited to US-only geography.

Bayer very much regretted the breaches of the Code that occurred as a result of the above and had taken steps to ensure no repeat of this was possible. Future Bayer US digital DTC campaigns would, by default, be limited to US-only geography and the Bayer US advertisement buying platform now had a default setting for US-only geography.

PANEL RULING

The Panel noted that the complaint concerned an advertisement for a prescription only medicine, Kerendia (finerenone), which appeared as two identical vertical banner advertisements on either side of an article about multiple sclerosis (MS), published within the Health section of the MailOnline.

The Panel noted that Kerendia was indicated for the treatment of chronic kidney disease (stages 3 and 4 with albuminuria) associated with type 2 diabetes in adults and that the banner advertisement was unrelated to the content of the article.

The Panel noted that, according to the information provided by Bayer, the banner advertisement at issue comprised of four revolving frames. The complainant had provided what appeared to be a partial screenshot of the fourth frame.

The Panel noted that the fourth frame of the banner advertisement at issue, beneath the brand logo and name, Kerendia, read 'Ask your doctor how Kerendia can help' in a bold, prominent font underneath which was a 'Learn More' tab and statement 'See the Important Safety Information and Prescribing Information below'. This was followed by a picture of an adult man and woman, and a bold heading 'Indication and Important Safety Information' followed by 'WHAT IS KERENDIA? Kerendia is a prescription medicine used to treat chronic kidney disease in adults with type 2 diabetes to…'. The copy of the fourth frame provided by Bayer showed that the text continued 'reduce the risk of:'. It appeared that the missing text, the balance of the 'Indication and Important Safety Information' was, according to the certified copy provided by Bayer, accessible on the fourth frame only, by scrolling. The notes on the certified copy implied that the scrolling function was not designed to work on the first 3 frames. The remainder of the 'Indication and Important Safety Information' detailed: what is Kerendia, important safety information on when not to take Kerendia, advice on telling your health professional about existing medical conditions and prescription and over the counter medicines that you take. This was followed by the most common side effects of Kerendia, and near the bottom bold prominent text stating 'PLEASE SEE THE PRESCRIBING INFORMATION FOR KERENDIA'.

The Panel noted that upon clicking the 'Learn more' tab in the fourth frame of the banner advertisement, readers were directed to what appeared to be the homepage of the Kerendia US website, which displayed the prominent brand name Kerendia and generic name finerenone at the top. There was a narrow menu banner at the top of the webpage containing the following tabs: 'For Healthcare professionals', 'Prescribing Information' and 'Important Safety Information'. Below, prominent text stated 'Have chronic kidney disease in type 2 diabetes (CKD in T2D)? There may be more you can do to help protect your kidneys. KERENDIA is proven to slow the progression of CKD in adults with T2D that could lead to kidney failure, dialysis, or kidney transplant.' The webpage included, amongst other things, buttons on 'I want to learn about KERENDIA', 'I am starting on Kerendia' and 'I want to learn about patient support programs for KERENDIA.' Near the bottom of the webpage there was a link to Prescribing Information, followed by 'Last updated 04/2022. This site is intended for US residents only.'

The Panel noted Bayer's submission that the US-originated Kerendia DTC (direct to consumer) National Digital Campaign posted by Bayer US, intended solely for availability and access in the US was inadvertently accessible in the UK. The Panel also noted Bayer's submission that the new advertisement buying software did not default to US only and the operator decision where the target geography was determined was overlooked and consequently defaulted to distribution outside the US, including the UK. The Panel noted that in accordance with an established principle under the Code, Bayer UK was responsible for the acts and omissions of its US affiliate that came within the scope of the Code.

The Panel noted that the US DTC category did not have an equivalent UK category and the Panel had to decide whether to apply the Code requirements in relation to promoting prescription medicines to health professionals and/or those that applied to the provision of information to the public. The Panel noted that the material at issue did not fit neatly within either UK category. The Panel decided the applicability of each clause on a matter by matter basis.

In the Panel's view, the banner advertisement, with multiple prominent mentions of the brand name of the prescription only medicine Kerendia, and in addition the link to a Kerendia US

website which was product-related, could not be considered as anything other than Kerendia promotional material and it was on this basis that the Panel made its rulings.

The Panel noted the identical requirements of Clauses 3.2 (an overarching requirement) and 26.1 of the Code which stated that prescription only medicines must not be advertised to the public. The Panel, noting the prominent display and multiple mentions of the brand name Kerendia on the banner advertisement, and that clicking on the fourth frame of the banner directed readers to a Kerendia US website, considered that the banner advertised a prescription only medicine to the public. The Panel noted that the complainant had raised one matter but cited two separate, yet identical, Clauses. The Panel considered that it would make one ruling that would apply equally to both Clauses and therefore ruled a breach which applied to both **Clauses 3.2 and 26.1**, as acknowledged by Bayer.

The Panel, noting the promotional nature of the advertisement, including the prominent statement 'Ask your doctor how Kerendia can help' on the banner, considered that the advertisement would likely encourage members of the public to ask their health professional to prescribe a specific prescription only medicine, and thus ruled a **breach of Clause 26.2**, as acknowledged by Bayer.

The Panel noted the complainant's allegation that it was impossible to scroll down the banner advertisement to display the prescribing information, date of preparation and instructions to report adverse events, therefore breaching the Code.

The Panel noted that the 'Indication and Important Safety Information' as provided by Bayer, the complete version of which was accessible by scrolling the relevant part of the fourth frame, contained a prominent statement 'PLEASE SEE THE PRESCRIBING INFORMATION FOR KERENDIA' with what appeared to be a link to the US prescribing information.

The Panel did not agree with Bayer's submission that the Code did not apply with regard to the requirement to include prescribing information and adverse event reporting statement as the banner advertisement was aimed at consumers/patients and not at health professionals. The Panel noted Bayer's arguments about the intended audience but considered that this applied to its intended publication in the US, rather than the UK where advertising prescription only medicines to the public was prohibited. The Panel noted that the text addressed members of the public in the US. The Panel considered that as the advertisement at issue had been published in the UK, it therefore had to comply with all the relevant UK requirements for such advertisements. The Panel noted its comments above about the applicability of Clauses and considered that an advertisement for a prescription only medicine published in the UK should comply with the relevant UK requirements for such advertisements irrespective of the fact that its intended audience was originally US members of the public. It had not been published in a forum where it would be read primarily by US members of the public. Clause 12.1 stated, amongst other things, that the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine. Clause 12.9 required, among other things, that all promotional material must include a prominent adverse event reporting statement.

The Panel noted its comments above, that in its view, the banner advertisement at issue was promotional, and that it did not appear that UK prescribing information was included in the material as required by Clause 12.1 nor the adverse event reporting statement as required by Clause 12.9. Whilst the Panel noted that the banner advertisement appeared to have a

hyperlink to prescribing information, the Panel noted that the banner was not intended for a UK audience and therefore it was unlikely to have met the requirements of Clause 12.1. The Panel therefore ruled a **breach of Clause 12.1** in relation to the omission of the UK prescribing information and a **breach of Clause 12.9** due to the omission of an adverse event reporting statement.

The Panel noted Bayer's submission that Bayer plc had identified the original Bayer US documentation which displayed the date of preparation. The Panel noted that the expanded version of the fourth frame of the banner stated the date March 2022 at the bottom, and the Panel ruled **no breach of Clause 12.8** in this regard.

Clause 26.4 stated, amongst other things, that any material which relates to a medicine and which is intended for patients taking that medicine must include a reporting of side effects statement. The Panel noted Bayer's submission that the US Kerendia DTC was a banner advertisement and not intended for patients who were already taking the medicine Kerendia.

The Panel noted that internal documentation provided by Bayer stated the purpose of the document 'These banners will be targeted toward CKD in T2D patients who are currently under the care of a nephrologist to encourage them to talk to their Neph about treatment with KERENDIA'. The Panel noted its comments above, that in its view the banner advertisement was promotional, and therefore queried whether Clause 26.4 was applicable. In any event, on the narrow technical point that the banner advertisement was considered to be promotional material, the Panel ruled **no breach of Clause 26.4**.

Clause 13.6 stated, among other things, that abbreviated advertisements must include a prominent adverse event reporting statement. The Panel noted Bayer's submission that it did not consider that the US Kerendia digital banner advertisement was subject to Clause 13.6 as it applied specifically to abbreviated advertisements. The Panel considered that the banner advertisement was published as a full advertisement albeit apparently with US prescribing information. The Panel did not consider that the banner advertisement at issue was an abbreviated advertisement and ruled **no breach of Clause 13.6** accordingly.

The Panel noted the complainant's allegation that as it was published in a public outlet, Bayer had breached Clause 13.2 of the Code, which stated, among other things, that abbreviated advertisements may only appear in professional publications. The Panel considered that its comments above applied here and did not consider that the banner advertisement at issue was an abbreviated advertisement and ruled **no breach of Clause 13.2** accordingly.

The Panel noted the complainant's allegation that because it was impossible to scroll down the banner advertisement to read more, Bayer had breached Clause 8 (UK certificate). In the Panel's view the complainant was referring specifically to Clause 8.1, which stated, among other things, that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified. The Panel did not consider that the banner advertisement at issue had been certified as required, and a **breach of Clause 8.1** was ruled, as acknowledged by Bayer.

Noting its comments above the Panel did not make a ruling on Clauses 8.2 to 8.6, as in its view, these were not raised or applicable.

Clause 16.1 stated that promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code. The Panel, noting its rulings of breaches of the Code above, considered that the banner advertisement at issue did not comply with the relevant requirements of the Code, and ruled a **breach of Clause 16.1**, as acknowledged by Bayer.

The Panel noted the complainant's allegation that because of the sheer amount of breaches, Bayer was in breach of Clause 5 (high standards and suitability). The Panel considered that given the matter raised was limited to the number of breaches the complainant's concerns were adequately covered by Clause 5.1 of the Code.

The Panel, whilst noting Bayer's submission that human error within Bayer US during the set-up of a US Kerendia DTC whereby geo-location settings were not restricted to the US inadvertently resulted in the Campaign being accessible in the UK, noted its comments and rulings of breaches of the Code above, and considered that Bayer had failed to maintain high standards and ruled a **breach of Clause 5.1**, as acknowledged by Bayer.

The Panel noted that examples of activities that were likely to be in breach of Clause 2 included prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorisation, conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

Clause 2 was a sign of particular censure and reserved for such use. The Panel was concerned that a banner advertisement for a prescription only medicine, which was published from 1 July until 16 August and was only withdrawn on receipt of the complaint, appeared on a UK news website and therefore would have been exposed to a wide UK audience including members of the public; in this regard the Panel queried why neither the US nor local affiliates had noticed that the distribution had defaulted to ex US.

The Panel, noting that the linked website to the banner advertisement was clearly intended for a US audience, and noting the complainant had limited their reason for an alleged breach of Clause 2 to the overall number of breaches, considered in the particular circumstances of this case that, on balance, a breach of Clause 5.1 adequately covered the matter and **no breach of Clause 2** was ruled accordingly.

Complaint received **11 August 2022**

Case completed **22 September 2023**