NO BREACH OF THE CODE

CASE AUTH/3569/10/21

COMPLAINANT v PIERRE FABRE

Alleged promotion of Nerlynx to the public

A complainant who described him/herself as a member of the public/media alleged that Nerlynx (neratinib maleate) had been promoted to the public.

The complainant alleged that an advertising agency had used materials that included the brand name and indication in the sponsorship of an awards event on an open website.

The detailed response from Pierre Fabre is given below.

The Panel noted Pierre Fabre's submission that following the complaint, the third party marketing agency confirmed that the material at issue included clips from a Pierre Fabre Global video approved for use outside of the UK. The Panel noted that the frame specifically identified by the complainant was titled 'In an oral, once-daily therapy' and included a cartoon image of a woman walking in the snow and stated within small text at the bottom of the frame 'Nerlynx is indicated for the extended adjuvant treatment of adult patients with early-stage HER2+/HR+ breast cancer'.

The Panel noted Pierre Fabre's submission that in 2019, Pierre Fabre Global had retained the named agency for creative copywriting and digital imagery services on discrete projects.

The Panel noted that it was a well-established principle that pharmaceutical companies were responsible for work undertaken by third parties on their behalf and that UK pharmaceutical companies were responsible for the activities of overseas affiliates that came within the scope of the UK Code which, based on the location of the Pharmaceutical Marketing Society, the material at issue on its awards website did.

According to Pierre Fabre, the Master Services Agreement (MSA) included a commitment to confidentiality, to comply with applicable laws, the EFPIA Code, Pierre Fabre Group procedures and Pierre Fabre Group Ethics and the MSA required Pierre Fabre to provide prior consent for any use by the agency of materials prepared by it on behalf of Pierre Fabre Global. The Panel noted Pierre Fabre's submission that the agency had failed to comply with its contractual commitments and without the prior knowledge or approval of Pierre Fabre UK, nor of Pierre Fabre Global, had posted the video at issue showing some of its work on a Pharmaceutical Marketing Awards site in relation to what appeared to the Panel to be the agency's sponsorship of the awards as opposed to an entry for an award.

The Panel acknowledged that creative agencies would want to showcase their work in certain circumstances including in relation to awards and that, as a result, examples of such work might appear, *inter alia*, on open-access websites. The Panel noted Pierre Fabre's submission that websites such as the one on which the material at issue

appeared were typically directed specifically at the creative media and the pharmaceutical industry and were not aimed at the general public. The Panel considered that although anyone could access the material on the pharmaceutical marketing awards website, it was not aimed at the general public. The Panel, noting its comments above, considered that, in the particular circumstances of this case, Nerlynx had not been promoted to the public and, on balance, no breach of the Code was ruled. The Panel considered that Pierre Fabre had been let down by an agency working on behalf of its global affiliate; there was no evidence that Pierre Fabre had failed to maintain high standards and no breach of the Code was ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2.

A complainant who described him/herself as a member of the public/media alleged that Nerlynx (neratinib maleate) had been promoted to the public.

Nerlynx was indicated for the extended adjuvant treatment of adult patients with early-stage hormone reception positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.

COMPLAINT

The complainant alleged that an advertising agency had used materials that had brand name and indication in the sponsorship of an awards event. A video was hosted on an open website and contained the materials in breach of Clause 2. The complainant provided a screenshot of the material and a link to the video and stated that the scenes could be found at 18 seconds on the link provided.

When writing to Pierre Fabre, the Authority asked it to consider the requirements of Clause 2 as cited by the complainant, as well as Clauses 5.1 and 26.1 of the 2021 Code.

RESPONSE

Pierre Fabre submitted that it was deeply concerned by the alleged breaches of the Code as the company were completely committed to it and had therefore taken this matter extremely seriously.

Pierre Fabre UK explained that it first became aware of the compilation video upon receiving the letter from the PMCPA. Included within the video were short clips of a Pierre Fabre Nerlynx video posted on a Pharmaceutical Marketing Awards site, and accessible via the link provided by the complainant.

Pierre Fabre stated that on 19 October 2021, the third party marketing agency confirmed in an email that the material at issue were clips from a Pierre Fabre Global video (NERL-IVID-WO-0003133 – February 2020) approved by Pierre Fabre Global for use outside of the UK (Global Feb 2020 video).

As part of its investigation into this complaint, Pierre Fabre UK compared the material at issue with another UK video (reference UK/NER/0079, UK January 2020 video) that repurposed an earlier global video initially approved for use outside the UK (Global September 2019 video). The objective of the UK video, certified on 10 January 2020 for internal use only, was to provide an introduction to the 'Nerlynx' section of the conference for all UK Pierre-Fabre employees

following its availability in the UK from October 2019. The third party marketing agency had no involvement in this UK video and Pierre Fabre UK had not used or modified the certified UK January 2020 video in any other way since.

Pierre Fabre submitted that it was clear that the video that the complainant referred to was not the UK January 2020 certified version (reference UK_NER_0079) since the UK disclaimers, UK job code number and date of preparation were not included.

Breaches of Contract between Pierre Fabre Global and the third party marketing agency

In 2019, Pierre Fabre Global retained the third party marketing agency on a non-exclusive basis for creative copywriting and digital imagery services on discrete projects. A Master Services Agreement (MSA) was negotiated in August 2019.

The terms of the MSA included a commitment to confidentiality, to comply with applicable laws, the EFPIA Code, Pierre Fabre Group procedures and Pierre Fabre Group Ethics. Sections 2.6, 5.1 and 5.4 of the MSA clearly required Pierre Fabre to provide prior consent for any use by the agency of materials prepared by it on behalf of Pierre Fabre Global.

The third party marketing agency failed to comply with its contractual commitments and had apologised for this.

Clause 26.1 – Pierre Fabre submitted that it did not promote to the public

Although Pierre Fabre appreciated that creative agencies entered their work for awards from time to time and that, as a result, examples of their work might appear on open access websites, such sites were typically directed specifically at the creative media and the pharmaceutical industry and were not aimed at the general public.

Whilst acknowledging this general point, in this case Pierre Fabre UK submitted that:

- 1 It was only made aware of this compilation video by the PMCPA complaint letter.
- 2 It did not give permission for any video to be used externally by Precision Effect the third party marketing agency or Pharmaceutical Marketing Society.
- 3 Pierre Fabre Global did not give permission for the Global February 2020 video (of which sections/frames were used in the compilation video) to be used externally by the third party marketing agency or Pharmaceutical Marketing Society.
- 4 The third party marketing agency breached the terms of the Pierre Fabre Global MSA as described above.
- 5 The website which hosted the compilation video was not directed to the public or to health professionals.

Clause 5.1 – Pierre Fabre submitted that it did maintain high standards

- 1 Pierre Fabre UK had repurposed the Global September 2019 video to make it fit for UK internal use and certified it as such in accordance with the Approval of Promotional and Non-Promotional Material Standard Operating Procedure (SOP).
- 2 The materials at issue were uploaded and made available without the prior knowledge or approval of Pierre Fabre UK, nor of Pierre Fabre Global.

- 3 Pierre-Fabre UK took decisive immediate steps to address the issues raised in the complaint: by immediately contacting the third party marketing agency and Pharmaceutical Marketing Society, ensuring that the video was removed with immediate effect on 18 October 2021 and began an investigation as per its Handling Complaints, Admissions and Undertakings SOP.
- 4 The possibility that members of the public could access the video at issue via the link provided by the complainant was not as a result of failure to maintain high standards on the part of Pierre Fabre UK or Pierre Fabre Global.

Therefore, Pierre Fabre believed it did not bring the industry into disrepute and, as such, was not in breach of Clause 2.

Pierre Fabre stated that it was disappointed and let down by the third party marketing agency's actions and would take all learnings from this case forward in its quest to drive compliance excellence when working with third parties.

Pierre Fabre UK wished to absolutely re-affirm its commitment to self-regulation, to the high standards set by the Code, and assure that this approach was applied throughout its Compliance Governance structure, its comprehensive procedures, covering all activities, and its rigour in training and briefing all employees.

Also, Pierre Fabre Global was fully committed to the EFPIA Code, its Code of Conduct and Code of Ethics and completely embraced a continuous improvement approach across all its compliance procedures.

PANEL RULING

The Panel noted the complainant's allegation that a video had been hosted on a pharmaceutical marketing awards website which contained the brand name of one of Pierre Fabre's products, NeryInx, and its indication. The Panel noted Pierre Fabre's submission that following the complaint, the third party marketing agency confirmed that the material at issue included clips from a Pierre Fabre Global video approved for use outside of the UK. The Panel noted that the frame specifically identified by the complainant was titled 'In an oral, once-daily therapy' and included a cartoon image of a woman walking in the snow and stated within small text at the bottom of the frame 'Nerlynx is indicated for the extended adjuvant treatment of adult patients with early-stage HER2+/HR+ breast cancer'.

The Panel noted Pierre Fabre's submission that in 2019, Pierre Fabre Global had retained the named agency for creative copywriting and digital imagery services on discrete projects. According to Pierre Fabre, the terms of the Master Services Agreement (MSA) negotiated in August 2019 included a commitment to confidentiality, to comply with applicable laws, the EFPIA Code, Pierre Fabre Group procedures and Pierre Fabre Group Ethics and Sections 2.6, 5.1 and 5.4 of the MSA required Pierre Fabre to provide prior consent for any use by the agency of materials prepared by it on behalf of Pierre Fabre Global. The Panel noted Pierre Fabre's submission that the agency had failed to comply with its contractual commitments and without the prior knowledge or approval of Pierre Fabre UK, nor of Pierre Fabre Global, had posted the video at issue showing some of its work on a Pharmaceutical Marketing Awards site in relation to what appeared to the Panel to be the agency's sponsorship of the awards as opposed to an entry for an award.

The Panel noted that it was a well-established principle that pharmaceutical companies were responsible for work undertaken by third parties on their behalf and that UK pharmaceutical companies were responsible for the activities of overseas affiliates that came within the scope of the Code which, based on the location of the PM Society, the material at issue on its website did. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public.

The Panel acknowledged that creative agencies would want to showcase their work in certain circumstances including in relation to awards and that, as a result, examples of such work might appear, *inter alia*, on open-access websites. The Panel noted Pierre Fabre's submission that websites such as the one on which the material at issue appeared were typically directed specifically at the creative media and the pharmaceutical industry and were not aimed at the general public. The Panel considered that although anyone could access the material on the pharmaceutical marketing awards website, it was not aimed at the general public. The Panel noting its comments above considered that, in the particular circumstances of this case, Nerlynx had not been promoted to the public and, on balance, no breach of Clause 26.1 was ruled. The Panel considered that Pierre Fabre had been let down by an agency working on behalf of its global affiliate; there was no evidence that Pierre Fabre had failed to maintain high standards and no breach of Clause 5.1 was ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2.

Case completed

5 July 2022