CASE AUTH/3435/12/20

COMPLAINANT v ALIMERA

Alleged promotion of Iluvien

A complainant who described him/herself as a concerned UK health professional complained about the promotion of Iluvien (fluocinolone acetonide) intravitreal implant on Alimera Sciences Limited's website (iluvien.co.uk).
The complainant stated that the initial page of the website which asked visitors to click on one of two options, 'For UK Healthcare Professionals' or 'For Patients and Public', mixed up patients on treatment with the general public. The complainant alleged that all of the links were clearly for patients on treatment, not for members of the general public and, as such, the website promoted to the general public.

The complainant further noted that the Iluvien prescribing information was difficult to read, probably due to the format with extremely long lines of text.

The detailed response from Alimera is given below.

The Panel noted that the landing page of the website in question had two clearly labelled sections; one titled 'For UK healthcare professionals' and the other titled 'For patients and public'. The section for health professionals had a hyperlinked box which stated 'Continue if you are a Healthcare Professional'. The section for patients and public stated 'Download patient guides', followed by four hyperlinked boxes to resources which included a patient information leaflet (PIL), a patient education leaflet and two treatment support booklets, one for each of Iluvien's indications which were stated in the hyperlinked boxes.

The Panel noted that it did not have a copy of the materials in question. Nonetheless, it was clear from the landing page that two of the documents were described as patient treatment support booklets and thus directed at those prescribed the product. The Panel was unsure how readers were directed to the website but noted that it appeared that those who arrived at the website were, from the landing page, able to view both indications for Iluvien, and download the relevant support booklets for each directly from the landing page. In the Panel's view, these booklets were specifically aimed at patients who had been prescribed Iluvien for each of the relevant indications and were not reference information for the general public as referred to in the Code. The Panel considered that those materials intended for patients for whom the prescribing decision had been made should only have been made available once the relevant target audience had been made clear and there should have been a separate section for the general public. The Panel, noting its comments above, and taking all of the circumstances into account, considered that the descriptions of the support booklets and the availability to download materials which were intended for those for whom the prescribing decision has been made, from what appeared to be an open access landing page, meant that the

landing page promoted Iluvien to members of the public. A breach of the Code was ruled as alleged.

The Panel noted that the Iluvien prescribing information was printed in grey font on a white coloured background. In that regard, the Panel considered that the contrast between the colour of the text and the background was not unacceptable and did not appear to render the text illegible. The Panel did not know upon what device the complainant had viewed the material and so in what size the text had appeared. However, the complainant's allegation about extremely long lines of text was consistent with Alimera's submission that the line length was 115 characters including spaces. The Panel considered that the line length was excessive and, on balance, would make the prescribing information difficult to read on certain devices. A breach of the Code was ruled.

The Panel considered that Alimera had failed to maintain high standards and a breach of the Code was ruled. It did not consider that the specific circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use.

A complainant who described him/herself as a concerned UK health professional complained about the promotion of Iluvien (fluocinolone) acetonide intravitreal implant on Alimera Sciences Limited's website (iluvien.co.uk).

Iluvien was indicated for the treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. Iluvien was also indicated for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

COMPLAINT

The complainant referred to the initial page of the website (screenshot provided which asked visitors to click on one of two options; 'For UK Healthcare Professionals' or 'For Patients and Public') and stated that it mixed up patients on treatment with the general public. The complainant alleged that all of the links were clearly for patients on treatment, not for members of the general public and, as such, the website promoted to the general public.

The complainant further noted that the Iluvien prescribing information (link provided) was difficult to read, probably due to the format with extremely long lines of text.

When writing to Alimera, the Authority asked it to consider the requirements of Clauses 2, 4.1, 9.1 and 26.1 of the Code.

RESPONSE

Alimera noted the complainant's allegation that it had promoted Iluvien to the general public on its website https://iluvien.co.uk/. As stated in the summary of product characteristics (SPC), Iluvien was indicated for the treatment of vision impairment associated with chronic diabetic macular oedema (DMO), considered insufficiently responsive to available therapies; and for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

Alimera stated that the website in question had content suitable for both health professionals and members of the public. The screenshot provided by the complainant was taken from the landing page of the website and showed that there were two distinct elements to the website. Alimera submitted that the health professional area was appropriately labelled and contained promotional information suitable only for health professionals. The area for patients and the public was also clearly labelled.

Alimera stated that upon entering the area for patients and the public, the landing page provided information about the product which was suitable for the general public. This included the information identified in the supplementary information to Clause 26.2 as being suitable reference material for the general public, namely the patient information leaflet plus some suitable booklets and materials. None of the items provided for the public were promotional. Iluvien patients were, by definition, limited in their sight, so it was highly appropriate that the material was accessible by their support network and carers.

Alimera submitted that while some of the information might be regarded as suitable for patients, it was not reserved for patients *per se* and there was no reason why members of the public could not see that content.

Clause 26.1 of the Code prevented the promotion of prescription only medicines to the public. Alimera stated that the public had not been provided with promotional material and had not been encouraged to enter the health professional side of the website. Alimera therefore denied any breach of Clause 26.1.

Alimera noted that the prescribing information, within the health professional area of the website, was clearly signposted. Screenshots of the prescribing information as it appeared on the website were provided.

Alimera submitted that the prescribing information was clear and legible as required by the supplementary information to Clause 4.1. Even from the A4-sized screenshot provided, the text was easily distinguishable from the background page. The letters and lines were clearly spaced. The beginning of each section was both emboldened and underlined.

Alimera noted that the Code no longer had a standalone limit of 100 characters per line, partly to recognise that much information was now provided online. Alimera stated that, including spaces, the line length was approximately 115 characters. The company denied a breach of Clause 4.1.

Alimera stated that it strove to achieve high standards in all of its activities. In this instance, Alimera did not consider that it had fallen below the requirements of the Code in that regard and it denied any breach of Clauses 9.1 or 2.

PANEL RULING

The Panel 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.

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. The Panel noted that whilst Clause 28.1 and its supplementary information did not specifically mention material for patients who had been prescribed a specific medicine, companies could, nonetheless, provide information about a specific medicine to patients for whom the prescribing decision had already been made so long as such information complied with the relevant requirements of the Code. In the Panel's view, the principles of the supplementary information to Clause 28.1 were relevant and the intended audience should be identified. When identifying the audience, companies should be clear about whether they were identifying patients in a broad sense or patients who had been prescribed a specific medicine.

The Panel noted Alimera's submission that upon entering the area for patients and the public, the landing page provided information about the product which included the information identified in the supplementary information to Clause 26.2 as being suitable reference material for the general public, namely the patient information leaflet plus some suitable booklets and materials and that none of the items were promotional. The Panel further noted Alimera's submission that while some of the information might be regarded as suitable for patients, it was not reserved for patients *per se* and there was no reason why members of the public could not see that content.

The Panel noted that the landing page of the website in question had two clearly labelled sections; one titled 'For UK healthcare professionals' and the other titled 'For patients and public'. The section for health professionals had a hyperlinked box which stated 'Continue if you are a Healthcare Professional'. The section for patients and public stated 'Download patient guides', followed by four hyperlinked boxes to resources which included a patient information leaflet (PIL), a patient education leaflet and two treatment support booklets, one for each of Iluvien's indications which were stated in the hyperlinked boxes.

The Panel noted that it did not have a copy of the materials in question. Nonetheless, it was clear from the landing page that two of the documents were described as patient treatment support booklets and thus directed at those prescribed the product. The Panel was unsure how readers were directed to the website but noted that it appeared that those who arrived at the website were, from the landing page, able to view both indications for Iluvien, and download the relevant support booklets for each directly from the landing page. In the Panel's view, these booklets were specifically aimed at patients who had been prescribed Iluvien for each of the relevant indications and were not reference information for the general public as referred to in Clause 26.2. The Panel considered that those materials intended for patients for whom the prescribing decision had been made should only have been made available once the relevant target audience had been made clear and there should have been a separate section for the general public. The Panel, noting its comments above, and taking all of the circumstances into account, considered that the descriptions of the support booklets and the availability to download materials which were intended for those for whom the prescribing decision has been made, from what appeared to be an open access landing page, meant that the landing page promoted Iluvien to members of the public. A breach of Clause 26.1 was ruled as alleged.

The Panel further noted the complainant's concern that the Iluvien prescribing information on the health professional section of the website was difficult to read, probably due to the format with extremely long lines of text. The Panel noted that Clause 4.1 required that prescribing information be provided in a clear and legible manner.

The Panel noted that the Iluvien prescribing information was printed in grey font on a white coloured background. In that regard, the Panel considered that the contrast between the colour of the text and the background was not unacceptable and did not appear to render the text illegible. The Panel did not know upon what device the complainant had viewed the material and so in what size the text had appeared. However, the complainant's allegation about extremely long lines of text was consistent with Alimera's submission that the line length was 115 characters including spaces. The Panel considered that the line length was excessive and, on balance, would make the prescribing information difficult to read on certain devices. A breach of Clause 4.1 was ruled.

The Panel noted its comments and rulings above and considered that Alimera had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel did not consider that the specific circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use and no breach of Clause 2 was ruled.

Complaint received **3 December 2020**

Case completed **30 June 2021**