

HEALTH PROFESSIONAL v SANTEN

Promotion of Cosopt to the public

A contactable complainant who described him/herself as a health professional, complained that a journal wrap-around advertisement (ref PP-CSPT-UK-0006) for Cosopt (dorzolamide and timolol) eye drops, placed in 'The Ophthalmologist', December 2020 by Santen UK Limited, was visible to the general public. The advertisement featured a picture of a soaring eagle. Cosopt was indicated in the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy was not sufficient.

The complainant stated the wrap-around advertisement for Cosopt was clearly visible through the plastic magazine wrapper and in that regard noted that medicines should not be advertised to the public. There was no active substance name and although the wrap-around stated that the prescribing information was overleaf, it was actually inside the wrap-around. This was misleading. The complainant alleged very poor practice from the company.

The complainant stated that he/she was also surprised with the imagery and that it was well known that eagles had superb vision, far superior to humans. The company should not be implying that Cosopt would improve the vision of the patient to that of an eagle.

The detailed response from Santen is given below.

The Panel noted that the material at issue was an advertisement wrapped around The Ophthalmologist journal. It would have to be removed before the journal could be read. The outside of the wrap-around included on the front the statement 'Preserve the freedom of sight with trusted power', followed by the image of an eagle. The bottom right of the advertisement included the Cosopt brand logo, followed by a claim and the indication for Cosopt. The statement 'Prescribing information and adverse event reporting information can be found overleaf' was included below the indication. The back of the outside of the wrap-around included an image of an eagle, alongside Santen's corporate logo, references for the claims, the date of preparation and a job code. The prescribing information for Cosopt was included on the inside of the wrap-around ie on the reverse of the front of the outside of the wrap-around.

In the Panel's view, the statement on the outside of the wrap-around that directed the audience to view the prescribing information 'overleaf' was not misleading as alleged. The reverse side of the wrap-around included the prescribing information. The Panel therefore ruled no breach of the Code.

The Panel considered that the context and audience of the advertisement were important. In the Panel's view, the imagery used would not imply that Cosopt would improve a

patient's vision to that of an eagle. Further the advertisement referred to preserving the freedom of sight. In the Panel's view, the audience would not be misled as alleged and the Panel therefore ruled no breach of the Code.

The Panel noted Santen's submission that due to a technical issue, the advertisement did not include the non-proprietary name. The certified copy of the advertisement included the non-proprietary name and this was also included in the version sent to the journal. It appeared that there was a printing error. As there was no non-proprietary name immediately adjacent to the most prominent display of the brand name in the final printed version, the Panel ruled a breach of the Code as acknowledged by Santen.

The Panel considered that because the journal with the wrap-around advertisement was visible in a transparent wrapper, this resulted in a prescription-only medicine being promoted to the public. The Panel ruled a breach of the Code, as acknowledged by Santen.

The Panel considered that Santen had failed to maintain high standards and ruled a breach of the Code.

A contactable complainant who described him/herself as a health professional, complained that a journal wrap-around advertisement (ref PP-CSPT-UK-0006) for Cosopt (dorzolamide and timolol) eye drops, placed in 'The Ophthalmologist', December 2020 by Santen UK Limited, was visible to the general public. The advertisement featured a picture of a soaring eagle. Cosopt was indicated in the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy was not sufficient..

COMPLAINT

The complainant referred to his/her copy of The Ophthalmologist (December 2020) which included a wrap-around advertisement for Cosopt that was clearly visible through the plastic magazine wrapper and in that regard noted that medicines should not be advertised to the public. Only the brand name was visible, the active substance name was missing completely, and the company name was only visible when the journal wrapper was removed and the back of the wrap-around advertisement was seen. The complainant noted that it was stated that the prescribing information was overleaf, but it was actually inside the wraparound. This was misleading. The complainant alleged very poor practice from the company.

The complainant stated that he/she was also surprised with the imagery and that it was well known that eagles had superb vision, far superior to humans. The company should not be implying that Cosopt would improve the vision of the patient to that of an eagle.

When writing to Santen, the Authority asked it to consider the requirements of Clauses 4.3, 4.7, 7.2, 9.1 and 26.1 of the Code.

RESPONSE

Santen stated that the material in question was a single page advertisement wrapped around the journal. The front of the advertisement contained the statement 'Prescribing information and adverse event reporting information can be found overleaf'. That was aligned to the

requirements of Clause 4.7, and Santen therefore denied breaches of Clause 4.7. Santen noted the complainant suggested it would be more accurate to state the prescribing information was 'inside the wrap-around', but Santen strongly denied that as it might imply that the information was inside the journal, which would be a clear breach of the Code.

Santen noted the complainant suggested the eagle image was intended to imply Cosopt would 'improve the vision of a patient to that of an eagle' and in that regard, by way of background the company explained that glaucoma was a common eye disease of the elderly, affecting 10% of people over 75 years of age. It was therefore a very common clinical problem encountered by ophthalmologists (the target audience of the journal). It was well known among health professionals in general, and especially within the specialist ophthalmology community, that visual loss caused by glaucoma was irreversible. Indeed, the guideline published by the National Institute for Health and Care Excellence (NICE) in 2017 clearly stated 'that once lost, sight cannot be recovered'. The National Eye Research Centre (NERC) reiterated that and stated that 'If left untreated, glaucoma can cause visual impairment, but if it is diagnosed and treated early enough, further damage to vision can be prevented'. NICE guidelines recommended a treatment approach of reducing intraocular pressure if patients were at risk of visual impairment. This in turn would protect sight, but not reverse any sight loss. The guidelines also stated that 'that most people having treatment for [chronic open angle glaucoma] will have good quality of life and not go blind'. Santen submitted that it would be highly unusual for specialist ophthalmologists, to whom the journal was targeted, to be unaware of the disease or treatment goals outlined above for glaucoma.

Santen noted that the headline claim of the advertisement was 'Preserve the freedom of sight' (emphasis added by Santen). That aligned exactly with the statement made by the NERC around preventing further damage to vision. The image of the eagle was used to reinforce that message in two ways. The bald eagle was a species that was protected to preserve its numbers in the wild. Furthermore, a bird represented freedom, and loss of sight would inevitably be a major disability that impacted on the freedom of individuals. The advertisement was intended therefore to show the overall goal of glaucoma therapy, to preserve sight through reductions in intraocular pressure; which was exactly in line with national guidelines. The word 'preserve' clearly stated just that, there was no suggestion, implicit or explicit, that sight would be 'improved' or indeed 'enhanced' to the capabilities of an eagle. Santen noted that the Cosopt summary of product characteristics (SPC) stated:

'Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss. This medicinal product reduces intra-ocular pressure without the common side effects of miotics such as night blindness, accommodative spasm and pupillary constriction.'

Santen thus strongly denied a breach of Clause 7.2, and any suggestions that the advertisement implied that sight could be improved, or indeed enhanced, by Cosopt.

With regard to the absence of the non-proprietary name, Santen regretfully acknowledged a breach of Clause 4.3 as the advertisement did not contain the generic name next to the most prominent display of the brand name.

Santen explained that the journal advertisement was commissioned and initially developed by Santen's EMEA (Europe, Middle East, and Africa) department as part of a wider advertising campaign across Europe. The UK version of the advertisement was sent for approval to the UK

review team. Following approval of the electronic version, the agency sent the electronic file of the advertisement to a local printer in the UK to obtain hard copies. The printer sent hard copies to Santen, and these were reviewed and certified by Santen UK (copy provided) and showed that the hard copies contained the generic name in the appropriate place. Following Santen UK approval, the same electronic file of the advertisement was sent to The Ophthalmologist by Santen's advertising agency. On receipt, an employee at The Ophthalmologist proceeded with uploading the file to the journal's systems to allow the publishing house to print the advertisements alongside the journal.

Santen submitted that its investigations had found that the electronic file of the advertisement was first checked by the agency involved in the project and that file contained the generic name exactly in line with the printed version that was certified. The Ophthalmologist was contacted, and it too confirmed the electronic file it received contained the generic name in line with the certified version. However, when the same electronic file was uploaded into The Ophthalmologist's remote system, the generic name was lost. The remote system was the tool The Ophthalmologist used to transfer files to its printing house - that system provided a visual representation of how the file would print (correspondence from the journal provided). Santen stated that the journal had also informed it that the publishing house performed no editing after the files were uploaded. The explanation provided by the publishing house as the 'most-likely' reason that the generic name had not printed was because the text part of the logo was set to 'overprint' rather than 'knockout'. That setting (used in print files) could cause errors in printing if not set correctly. However, and as outlined above, the *same* electronic file was used successfully to print the hard copy certified version in the UK. To further confirm that, Santen asked the agency to again send the same electronic file to the printer which provided the original hard copies that had been certified. This was performed on 16 February 2021 (copy provided). That showed that when printed the generic name was retained. Santen therefore concluded that the generic name was omitted due to technical reasons relating to the way the print file was processed at The Ophthalmologist.

Whilst Santen regretfully acknowledged a breach of the Code, at no time did Santen intend to breach the Code; on this occasion it had been let down by a technical issue at the journal that could not have been predicted, given that Santen's own printed versions were correct.

As noted above, the advertisement was commissioned by the EMEA team as part of a wider campaign across European journals. Santen knew that The Ophthalmologist was provided to health professionals in a plastic wrapper with one opaque side. However, the EMEA employee did not request the wrapper be opaque for the edition in question, and as such Santen regretfully acknowledged a breach of Clause 26.1.

Santen noted that it took its responsibilities with respect to the Code extremely seriously, and in its entire history it had had no upheld breaches of the Code. The circumstances of this case were regretful, and the company had already taken robust actions to mitigate future issues.

1. Santen had rechecked its impending and future advertising plans to ensure adherence to the Code.
2. All EMEA employees responsible for advertising had already been given further training to ensure adherence to relevant clauses in relation to journal advertising.
3. Any journal advertising issued by Santen must now be checked after publishers downloaded the file to their systems.

A copy of training slides and training records were provided.

In conclusion, Santen strongly denied breaches of Clause 4.7 and 7.2. Although the company acknowledged breaches of Clause 26.1 and 4.3, it had been badly let down by a technical issue at The Ophthalmologist, and at no time had Santen, implicitly or explicitly, intended to breach the Code. Santen noted that it had always taken its regulatory responsibilities extremely seriously and had not previously been found in breach of the Code. Santen stated that it had taken robust measures to both investigate the complaint and put in place measures to prevent future issues. Santen denied its actions were worthy of a breach of Clause 9.1, which did not in any way reflect the culture or philosophy of Santen UK, nor the nature and speed of its investigation and corrective actions.

PANEL RULING

The Panel noted that the material at issue was an advertisement wrapped around The Ophthalmologist journal. It would have to be removed before the journal could be read. The outside of the wrap-around included on the front the statement 'Preserve the freedom of sight with trusted power', followed by the image of an eagle. The bottom right of the advertisement had the Cosopt brand logo, followed by the claim 'Tried. Tested. Trusted' and the indication for Cosopt. The statement 'Prescribing information and adverse event reporting information can be found overleaf' was included below the indication. The back of the outside of the wrap-around included an image of an eagle, alongside Santen's corporate logo, references for the claims, the date of preparation and a job code. The prescribing information for Cosopt was included on the inside of the wrap-around ie on the reverse of the front of the outside of the wrap-around.

The Panel noted that Clause 4.7 stated, *inter alia*, that in the case of a printed journal advertisement where the prescribing information appeared overleaf, at either the beginning or the end of the advertisement, a reference to where it could be found must appear on the outer page of the other page of the advertisement in a type size such that a lower case 'x' was no less than 2mm in height. In the Panel's view, the statement on the outside of the wrap-around that directed the audience to view the prescribing information 'overleaf' was not misleading as alleged. The reverse side of the wrap-around included the prescribing information. The Panel therefore ruled no breach of Clause 4.7.

The Panel noted Santen's submission that the use of the image of an eagle and the headline claim 'Preserve the freedom of sight' was intended to show the overall goal of glaucoma therapy; to preserve sight through reductions in intraocular pressure.

The Panel further noted Santen's submission that the visual loss caused by glaucoma was irreversible and would be well known among health professionals in general, and especially for the target audience which were ophthalmologists. The Panel considered that the context and audience of the advertisement were important. In the Panel's view, the imagery used would not imply that Cosopt would improve a patient's vision to that of an eagle. Further the advertisement referred to preserving the freedom of sight. In the Panel's view the audience would not be misled as alleged and the Panel therefore ruled no breach of Clause 7.2.

The Panel noted Santen's submission that due to a technical issue, the advertisement contained the brand name of the medicine Cosopt but not the non-proprietary name. The certified copy of the advertisement included the non-proprietary name and this was also included in the version sent to the journal. It appeared that there was a printing error. However

as there was no non-proprietary name immediately adjacent to the most prominent display of the brand name in the final printed version, the Panel ruled a breach of Clause 4.3 as acknowledged by Santen.

The Panel noted the advertisement was commissioned by the Santen EMEA team which had not requested that the journal be sent in an opaque wrapper. The Code required under Clause 9.8 that envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 26.1. The Panel considered that because the journal with the wrap-around advertisement was visible in a transparent wrapper, this resulted in a prescription-only medicine being promoted to the public. The Panel ruled a breach of Clause 26.1, as acknowledged by Santen.

The Panel noted its comments and rulings above with regard to the promotion of a prescription only medicine to the public and the failure to include the non-proprietary name adjacent to the most prominent display of the brand name. The Panel considered that Santen had failed to maintain high standards and ruled a breach of Clause 9.1.

Complaint received **21 January 2021**

Case completed **17 June 2021**