

COMPLAINANT v SANOFI

Online advertisement

A complaint was received from an individual of unknown professional status, who complained about an online advertisement for Praluent (alirocumab) placed by Sanofi in the HSJ (Health Service Journal). Praluent was a lipid lowering agent. The advertisement in question was headed 'Advertorial: PCSK9 inhibitors – Recognising innovation in cholesterol treatment to help address a UK health burden' and discussed the use of Praluent. Prescribing information for Praluent was included.

The complainant was surprised to find the advertisement in an online journal with information on how to prescribe. The complainant was concerned that members of the public could subscribe to the HSJ [Health Service Journal] and so the website was not a suitable medium for an article about the benefits of prescribing a specific medicine.

The complainant noted that each reference had a hyperlink and queried whether Sanofi had permission from each of the website owners to create these hyperlinks eg, with the National Institute for Health and Care Excellence (NICE) or the British Heart Foundation. The complainant stated that he/she had been unable to find or access some of the references through the links provided.

The complainant noted that the material in question appeared to focus on the clinical aspects of treatment which he/she considered was more appropriate for doctors and not for the mixed readership of the HSJ.

The detailed response from Sanofi is given below.

The Panel noted that the Code covered the promotion of medicines to health professionals and to other relevant decision makers. These were defined as particularly those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. The Panel also noted previous cases involving advertising in the HSJ which was a specialist professional journal not aimed at the general public. In the Panel's view it was acceptable for companies to advertise medicines in the HSJ provided the advertisement was appropriate for the audience. The Panel considered that this also applied to the HSJ website where the advertisement in question had been placed.

The Panel noted the information provided by Sanofi about the target audience for the material in question, the website readership statistics and that the HSJ was intended for healthcare leaders or others who had a direct or indirect role in decision making within the NHS.

The content of the advertisement was broad and included information on the economic impact of cardiovascular disease, efficacy, side effects, tolerability and NICE recommendations. There was no mention of costs in the body of the advertisement; the only mention was in the prescribing information which included the list price of Praluent. The Panel did not consider that the inclusion of clinical content and references to clinical evidence meant that the advertisement was not tailored to the HSJ website audience.

On balance, the Panel was satisfied that the advertisement was sufficiently tailored to the HSJ audience and in that regard the audience could reasonably be assumed to have an interest in it. The Panel therefore ruled no breach of the Code in this regard.

The Panel did not consider that the advertisement for Praluent on the HSJ website was an advertisement to the public who subscribed to the HSJ as alleged. The HSJ was for those with a role in healthcare including health professionals. The Panel therefore ruled no breach in this regard.

The Panel noted the complainant stated that he/she had not been able to access the references. The links were not working. It was not clear whether the complainant had asked Sanofi to supply the references. Sanofi had not responded to this point nor had it responded as to whether it had permission from each of the website owners to create these hyperlinks. The Panel considered that if links were used in advertisements then they should work. The Code required substantiation to be provided on request and on the information available to the Panel there had been no request.

Given its rulings above the Panel considered that there had not been a failure to maintain high standards and ruled no breach of the Code.

An individual of unknown professional status complained about an online advertisement for Praluent (alirocumab) placed by Sanofi in the HSJ (Health Service Journal). Praluent was a lipid lowering agent. The advertisement in question was headed 'Advertorial: PCSK9 inhibitors – Recognising innovation in cholesterol treatment to help address a UK health burden' and discussed the use of Praluent. Prescribing information for Praluent was included. The piece was dated 25 June 2018.

COMPLAINT

The complainant stated that he/she was surprised to find the advertisement in an online journal with information on how to prescribe. The complainant was concerned that members of the public could

subscribe to the HSJ [Health Service Journal] and so he/she did not consider that the website was a suitable medium for an article about the benefits of prescribing a specific medicine.

The complainant noted that each reference had a hyperlink and queried whether Sanofi had permission from each of the website owners to create these hyperlinks eg, with the National Institute for Health and Care Excellence (NICE) or the British Heart Foundation. The complainant stated that he/she had been unable to find or access some of the references through the links provided.

The complainant noted that the material in question appeared to focus on the clinical aspects of treatment which he/she considered more appropriate for doctors and not for the mixed readership of the HSJ.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 9.1, 11.1, 26.1 and 26.2 of the 2016 Code.

RESPONSE

Sanofi stated that the advertorial in question was posted on the HSJ website rather than being included in an online journal.

In relation to the target audience for the advertorial, the HSJ website showed 18% of its readers were commissioners, 20% were from the private sector, 32% were healthcare providers and 27% were involved in commissioning.

Sanofi noted that the HSJ website and HSJ logo contained the wording 'For Healthcare Leaders' which indicated to the audience that the website was intended for healthcare leaders or others who had a direct or indirect role in decision-making within the NHS.

Sanofi submitted that the inclusion of pharmaceutical company advertising in the HSJ had previously been considered (Case AUTH/2058/10/07, Cases AUTH/2426/8/11 and AUTH/2427/8/11) when the Panel concluded that it did not accept that an advertisement in the HSJ constituted *per se* an advertisement to the public and it also 'considered that the publication was an acceptable vehicle for the advertisement of prescription only medicines' (Cases AUTH/2426/8/11 and AUTH/2427/8/11). In Case AUTH/2058/10/07 the Panel's view was that 'it was acceptable for companies to advertise medicines in the HSJ provided the advertisement was appropriate for the audience'.

Sanofi submitted that the placement of the advertisement on the HSJ website did not constitute promotion to the public and as such it denied breaches of Clauses 26.1 and 26.2.

The content of the advertisement was tailored to an audience of clinical and non-clinical health professionals and other relevant decision makers in line with the readership of the HSJ website. As such Sanofi denied a breach of Clause 11.1.

The advertisement highlighted the disease burden as an introductory statement and preface which made relevant reading for the clinicians and non-clinical decision makers alike. The first part of the advertisement was entirely dedicated to highlighting the disease burden; it explained the impact of cardiovascular disease in general on morbidity and mortality, healthcare and economic costs and discussed the relevant social impact. This section also discussed the current therapies used for lipid lowering and the societal impact on cardiovascular disease with specific reference to LDL C and cholesterol levels. It highlighted the clinical unmet need in optimum lipid management with specific focus on familial hypercholesterolemia which related to the impact on society, economic framework and healthcare. The sections on disease burden, unmet need and economic/social impact were of greater relevance to the non-clinical decision makers involving commissioners and policy makers who might be unaware of these aspects of the disease burden or unmet need especially with regards to Praluent. In Sanofi's view, this information would be of significant relevance in their decision making process.

Sanofi submitted that the second part of the advertisement looked at the clinical efficacy measure for Praluent in general and mentioned the relevant clinical evidence that related to the unmet need and disease burden which was highlighted in the first part of the advertisement. Whilst this was clinical data it was of significant relevance to the non-clinical decision makers since it crucially helped provide a plug in response to the level of unmet need that was highlighted. The commissioners and policy makers needed to be informed of the clinical efficacy of Praluent while responding to the challenge of the unmet clinical need in their local and regional environments.

This was of even more importance while considering the gap in uptake in the NICE recommended population that had been highlighted in the second part of the advertisement.

In conclusion, Sanofi refuted any breach of Clauses 11.1, 26.1 or 26.2 and thus of Clause 9.1.

PANEL RULING

The Panel noted that the Code covered the promotion of medicines to health professionals and to other relevant decision makers. These were defined as particularly those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. The Panel also noted previous cases involving advertising in the HSJ. The HSJ was a specialist professional journal and was not aimed at the general public. In the Panel's view it was acceptable for companies to advertise medicines in the HSJ provided the advertisement was appropriate for the audience. The Panel considered that this also applied to the HSJ website where the advertisement in question had been placed.

Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated that promotional material should be tailored to the audience to whom it was directed.

The Panel noted the information provided by Sanofi about the target audience for the material in question, the website readership statistics and that the HSJ was intended for healthcare leaders or others who had a direct or indirect role in decision making within the NHS.

The content of the advertisement was broad and included information on the economic impact of cardiovascular disease, efficacy, side effects, tolerability and NICE recommendations. There was no mention of costs in the body of the advertisement; the only mention was in the prescribing information which included the list price of Praluent. The Panel did not consider that the inclusion of clinical content and references to clinical evidence meant that the advertisement was not tailored to the HSJ website audience.

On balance, the Panel was satisfied that the advertisement was sufficiently tailored to the HSJ audience and in that regard the audience could reasonably be assumed to have an interest in it. The Panel ruled no breach of Clause 11.1.

The Panel did not consider that the advertisement for Praluent on the HSJ website was an advertisement to the public who subscribed to the HSJ as alleged. The HSJ was for those with a role in healthcare including health professionals. The Panel therefore ruled no breach of Clauses 26.1 and 26.2.

The Panel noted the complainant stated that he/she had not been able to access the references. The links were not working. It was not clear whether the complainant had asked Sanofi to supply the references. Sanofi had not responded to this point nor had it responded as to whether it had permission from each of the website owners to create these hyperlinks. The Panel considered that if links were used in advertisements then they should work. The Code required substantiation to be provided on request and on the information available to the Panel there had been no request. Sanofi was welcome to send the references to the PMCPA for it to send them to the complainant.

Given its rulings above the Panel considered that there had not been a failure to maintain high standards and ruled no breach of Clause 9.1.

Complaint received **7 January 2019**

Case completed **24 April 2019**