CASE AUTH/3238/8/19

ANONYMOUS v VIFOR

Corporate Website

An anonymous, non-contactable individual, who described him/herself as a 'concerned UK health professional', drew attention to the webpages for IV irons on Vifor Pharma UK Limited's corporate website and complained that the inverted equilateral triangle symbols were variously blue, grey or white and not black.

The complainant was unclear as to whether the website was intended for the public or for health professionals as it included links to download leaflets for either patients or clinicians about IV irons.

The detailed response from Vifor is given below.

The Panel noted that the website at issue was Vifor's corporate website which appeared to provide general information about the company. In the Panel's view, although not clearly stated by Vifor, the website had to be non-promotional given that the company expected it to be accessed by the general public/patients and in that regard the Panel noted from material provided by the complainant that none of the webpages which dealt with products had URLs which referred to health professionals.

The Panel noted that the complainant had referred to links to information leaflets for either patients or health professionals about IV irons but had not provided copies of those leaflets; copies were provided by Vifor. The Panel noted Vifor's submission that four of the five UK documents which were downloadable from the Ferinject (ferric carboxymaltose) webpage of the products section of the website were non-promotional items relating to formal risk management materials requested by the European Medicines Agency (EMA) and the Medicines and Healthcare product Regulatory Authority (MHRA). The two letters to health professionals had been jointly issued by Pharmacosmos, Vifor and Fresenius Medical Care and alerted readers to the risk of serious hypersensitivity reactions with IV iron products. The two leaflets, one for health professionals and one for patients, discussed the same matter. The fifth downloadable document, however, was published by the Scottish Medicines Consortium (SMC) in 2011 and detailed its assessment of Ferinject, stating that the product was accepted for restricted use in NHS Scotland. The document presented evidence on, *inter alia*, comparative efficacy, clinical effectiveness, cost of relevant comparators and budget impact. In the Panel's view the SMC document, although non-promotional *per se*, had been used for a promotional purpose. The document, specifically about Ferinject, had been placed by Vifor on its corporate website and it clearly contained claims for the product. The Panel thus considered that, overall, the website was promotional.

The Panel noted Vifor's submission that it had immediately deactivated the website at issue when it was informed of the complaint; the company had also removed all brand information from the site.

In the Panel's view, the inverted black triangle was a well-known and established symbol for health professionals. Its appropriate use was an important part of medicines regulation and contributed towards patient safety; failure to publish the triangle in the correct colour was, at the very least, inappropriate and might potentially cause confusion. As the product webpages on Vifor's corporate website were, in the Panel's view, promotional and the inverted triangles on those pages were not black, a breach of the Code was ruled as acknowledged by the company.

The Panel noted that the Code stated that promotional material about prescription only medicines directed at a UK audience which was provided on the Internet must comply with all the relevant requirements of the Code. The supplementary information 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. This was to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them.

The Panel noted that the corporate website provided promotional information for health professionals and information for the public but there was no separation of the material – it was all presented together. A breach of the Code was ruled as acknowledged by Vifor.

An anonymous, non-contactable individual who described him/herself as a 'concerned UK health professional' complained that the inverted equilateral triangle symbols on Vifor Pharma UK Limited's corporate website were not black.

COMPLAINT

The complainant provided a screen shot from the website and noted that there were various different versions of the inverted triangle symbol on the webpage about Ferinject (ferric carboxymaltose). The complainant stated that blue and grey triangles were immediately obvious and when a cursor was hovered over the drop-down list of the 'Products' tab a white triangle was visible. The complainant submitted that the same appeared to be so for the webpages about Venofer (iron sucrose (iron (III)-hydroxide sucrose complex) and Velphoro (sucroferric oxyhydroxide).

The complainant understood that the inverted triangle symbols should always be black; he/she considered that blue, grey or white triangles would confuse patients or health professionals visiting the website.

The complainant also stated that it was not clear whether the website was intended for the public or for health professionals as it included links to download leaflets for either patients or clinicians about IV irons.

When writing to Vifor, the Authority asked it to consider the requirements of Clauses 4.10 and 28.1 of the Code.

RESPONSE

Vifor submitted that it took compliance with the Code extremely seriously and had deactivated the corporate site with immediate effect. Vifor's investigation showed that the site included the correct black triangle until late June. The issue appeared to occur when an update to the website was uploaded incorrectly. Vifor was investigating how the error had occurred and once the root cause was identified it would amend the internal approval process to ensure that it could not happen again. In addition, Vifor had removed all brand information from the corporate site. Vifor accepted a breach of Clauses 4.10 and 28.1 and was extremely disappointed that an upload error could have resulted in such an obvious lack of compliance.

In response to a request for further information Vifor provided copies of the materials directed at a UK audience which could be downloaded from the Ferinject product webpage either for patients or for health professionals. Vifor stated that four of the five materials; an Article 31 letter dated 31 October 2013, a 'Dear Dr' letter dated January 2015, an IV iron leaflet for clinicians in the UK and an IV iron leaflet for patients in the UK were non-promotional items relating to formal risk management materials requested by the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) and did not require formal certification or approval certificates. Vifor stated that whilst the 'Dear Dr' letter had a certificate, the other three items did not. Vifor submitted that it was also unable to provide a certificate for the fifth item, a Scottish Medicines Consortium (SMC) Ferinject document. Vifor provided the approval certificate for the website and submitted that it was a corporate website intended to be about Vifor Pharma UK in general and not a specific medicine. According to Vifor the website was aimed at the general public which might include health professionals with an interest in iron deficiency and patients who had received IV iron, hence the availability of the materials above.

PANEL RULING

The Panel noted that the website at issue was Vifor's corporate website which appeared to provide general information about the company with tabs for 'About Vifor Pharma UK', 'Products', 'R&D', 'Careers', 'Media' and 'Contact'. Vifor had submitted that the website was not intended to be about a specific medicine and that the website was aimed at the general public which might include health professionals with an interest in iron deficiency and patients who had received IV iron. In the Panel's view, although not clearly stated by Vifor, the website had to be non-promotional given that the company expected it to be accessed by the general public/patients and in that regard the Panel noted from material provided by the complainant that none of the webpages which dealt with products had URLs which referred to health professionals.

The Panel noted that the complainant had referred to links to information leaflets for either patients or health professionals about IV irons but had not provided copies of those leaflets; copies were provided by Vifor. The Panel noted Vifor's submission that four of the five UK documents which were downloadable from the Ferinject webpage of the products section of the website were non-promotional items relating to formal risk management materials requested by the EMA and the MHRA. The two letters to health professionals had been jointly issued by Pharmacosmos, Vifor and Fresenius Medical Care and alerted readers to the risk of serious hypersensitivity reactions with IV iron products. The two leaflets, one for health professionals and one for patients, discussed the same matter. The fifth downloadable document, however, was published by the SMC in 2011 and detailed its assessment of Ferinject, stating that the product was accepted for restricted use in NHS Scotland. The document presented evidence on, *inter alia*, comparative efficacy, clinical effectiveness, cost of relevant comparators and

budget impact. In the Panel's view the SMC document, although non-promotional *per se*, had been used for a promotional purpose. The document, specifically about Ferinject, had been placed by Vifor on its corporate website and it clearly contained claims for the product. The Panel thus considered that, overall, the website was promotional.

The Panel noted Vifor's submission that it had immediately deactivated the website at issue when it was informed of the complaint; the company had also removed all brand information from the site.

The Panel noted that Clause 4.10 stated that when required by the licensing authority, all promotional material must show an inverted black equilateral triangle to denote that additional monitoring was required in relation to adverse reactions. In the Panel's view, the inverted black triangle was a well-known and established symbol for health professionals. Its appropriate use was an important part of medicines regulation and contributed towards patient safety; failure to publish the triangle in the correct colour was, at the very least, inappropriate and might potentially cause confusion. Additionally, Clause 26.3 required that if material about a medicine which was subject to additional monitoring was intended for patients taking that medicine, then the inverted black triangle symbol must be included with a statement to encourage the reporting of side effects. The Panel noted that Vifor had only been asked to consider the requirements of Clause 4.10. As the product webpages on Vifor's corporate website were, in the Panel's view, promotional and the inverted triangles on those pages were not black, a breach of Clause 4.10 was ruled as acknowledged by the company.

The Panel noted that Clause 28.1 stated that promotional material about prescription only medicines directed at a UK audience which was provided on the Internet must comply with all the relevant requirements of the Code. 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. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them.

The Panel noted that the corporate website provided promotional information for health professionals and information for the public but there was no separation of the material – it was all presented together. A breach of Clause 28.1 was ruled as acknowledged by Vifor.

Complaint received **12 August 2019**

Case completed **26 March 2020**