CASE AUTH/2890/11/16

HEALTH PROFESSIONAL v NOVO NORDISK

Company website

A health professional who until recently worked in the pharmaceutical industry, complained about Novo Nordisk's company websites. One website was the corporate website and the other was a resource website for health professionals.

In relation to the corporate website the complainant was concerned that patients were identified by both their condition but also by a picture and their full name. This was inappropriate.

The complainant noted that there were more patients in the diabetes section regarding patient videos. These videos were on the same website as the many injectable treatments for diabetes and the patients' testimonies focussed mainly on injectable therapy with little time given to oral therapies, which even if the argument was made that this section on a promotional website was not product specific, this clearly indirectly focussed on Novo Nordisk products.

The complainant alleged that one patient, even stated 'Then three years ago, my doctor prescribed me a once-daily injection and it's utterly transformed my life' which was disturbing hyperbole. Although this was not directly related to a product, it was hosted on a website where several once daily injectable medicines were promoted and the complainant did not see what conclusion would be reached other than that those treatments provided those results.

The complainant was concerned that it was not clear whether any of the patient testimonies had been reviewed since 2014.

In a section of the website dealing with hormone replacement therapy (HRT), a booklet entitled 'After the Menopause' was available to download. The complainant stated that it was not clear who had final editorial control of the piece. It was stated that the booklet was written by one person but beneath his/her name it was stated that the booklet was produced by Novo Nordisk. The complainant noted that it was also unclear whether the booklet had been reviewed since 2014.

The detailed response from Novo Nordisk is given below.

The Panel noted that although the complainant had accessed the health professional section of the corporate website, the patient section had much the same information on it including the patient pictures and videos.

In the Panel's view there was no reason not to use the patients' names on the corporate website and noted Novo Nordisk's submission that patients had provided the appropriate consent. In that regard the Panel considered that high standards had been maintained. No breach of the Code was ruled.

The Panel noted that the section of the website which dealt with diabetes included, *inter alia*, a link to Novo Nordisk products and a separate link to a patient video gallery. One of the patients featured in the video gallery had type 2 diabetes; he stated 'my doctor prescribed me a once-daily injection and it's utterly transformed my life. I can walk for miles with the dogs, play football with the grandkids, and I feel great'. The Panel noted Novo Nordisk's submission that the quotation had been taken out of context. At the start of the interview, the patient referred to going for long walks and eating healthily, both of which had a positive impact on his weight and hyperglycaemia. However, in the Panel's view the patient implied that despite this change 14 years ago, it was only three years ago when the once-daily injection was prescribed, that his life was 'utterly transformed'. One of the once-daily injections that the patient could have been prescribed was Novo Nordisk's product Victoza (liraglutide), information about which was available via the link to Novo Nordisk's products, although other once-daily injections for type 2 diabetes were available. Nonetheless, the Panel considered that it was exaggerated to state that a medicine 'utterly transformed' a life with the implication that it alone enabled the patient to walk miles and play football with children. The Panel noted that the Code required that information about prescription only medicines to the public must not raise unfounded hopes of successful treatment. Given that the patient video was available on the patient section of the website, the Panel ruled a breach of the Code. The Panel did not consider that the patient video constituted an advertisement for a prescription only medicine to the public and in that regard it ruled no breach of the Code.

The Panel noted Novo Nordisk's submission that the case studies were finally recertified more than two years after first being certified. In that regard the Panel ruled a breach of the Code.

The Panel noted that the front cover of the booklet entitled 'After the Menopause A personal guide for women' gave the independent author's details, below which was a statement that the booklet had been produced by Novo Nordisk. The Panel noted that Novo Nordisk had acknowledged that it was responsible for the content of the booklet. However, the statement 'Produced by Novo Nordisk' gave no indication as to the company's involvement, if any, in its content. The Panel ruled a breach of the Code.

The Panel noted that the booklet was re-certified within two years of the previous certification. The Panel thus ruled no breach of the Code.

The complainant noted that the resources available for health professionals to download from the professional resource website included several clinical papers. In the case of Victoza resources, this directed to a separate website to download the paper, whereas the Xultophy (insulin degludec/ liraglutide) section did not. The complainant stated that although these papers were on a promotional website and were solely for the promoted products, there was no evidence that they had been reviewed to ensure that no material was off licence and there was no prescribing information on any of the items. It was therefore impossible to know when, and if, the articles were last reviewed.

The Panel noted that the website was for health professionals only; they were directed to it as a professional resource via representatives and/or promotional material. Health professionals were also directed to the site via the corporate website. The clinical papers reprints were, according to Novo Nordisk's submission, the references used in the current marketing campaigns for Victoza and Xultophy. The Panel considered that upon visiting the website and possibly downloading the reprints, relevant prescribing information should, at the same time, be available to the health professional and in that regard it noted that prescribing information could be accessed via a separate but prominent link in the same screenshot as the reprints. The link to the prescribing information was clear. No breaches of the Code were ruled.

A health professional who until recently worked in the pharmaceutical industry, complained about a number of matters on Novo Nordisk's company websites. One website was the corporate website and the other was a resource website which was only for health professionals.

When writing to Novo Nordisk, the Authority asked it to bear in mind the requirements of Clauses 4.1, 4.6, 9.10, 14.5, 26.1, 26.2 and 9.1 of the Code.

1 Corporate website

COMPLAINT

The complainant stated that he/she had the following concerns about Novo Nordisk's corporate website:

Throughout the website, patients were identified by both their condition but also by a picture and their full name. The complainant did not consider that this was appropriate. The complainant referred in particular to patients who were pictured and named in a section of the website which dealt with haemostasis.

The complainant noted that in the part of the website which dealt with diabetes there were more patients in the section regarding patient videos. These videos were on the same website as were the many injectable treatments for diabetes and the patients' testimonies focussed mainly on injectable therapy with little time given to oral therapies, which even if the argument was made that this section on a promotional website was not product specific, this clearly indirectly focussed on Novo Nordisk products.

The complainant noted that one named patient (ref UK/WB/1014/0036) even stated 'Then three years ago, my doctor prescribed me a once-daily injection and it's utterly transformed my life' which was disturbing hyperbole. Although this was not directly related to a product, it was hosted on a website where several once daily injectable medicines were promoted and the complainant did not see what conclusion would be reached other than that those treatments provided those results.

The complainant stated that it was not clear whether any of the patient testimonies had been reviewed since 2014 which was concerning.

In a section of the website dealing with hormone replacement therapy (HRT), a booklet entitled 'After the Menopause' (ref UK/HRT/0412/0001(1)) was available to download. The complainant stated that it was not clear who had final editorial control of the piece. It was stated that the booklet was written by one person but beneath his/her name it was stated that the booklet was produced by Novo Nordisk. The complainant queried who chose what to write. The complainant noted that it was also unclear whether the booklet had been reviewed since 2014.

RESPONSE

Novo Nordisk responded to the various points raised by the complainant:

Use of patient profiles

Novo Nordisk stated that its corporate website was a non-promotional resource. The use of patient profiles was intended to bring to life the conditions for which Novo Nordisk had therapies. The use of real life patients gave a more representative and realistic image of people living with these conditions than images of models who were, in reality, not actual patients. Appropriate consent and permissions had been gained in order for Novo Nordisk to use the images of the patients.

Patient quotation

Novo Nordisk had a consent form for patient interviews. The form was signed by a named patient in July 2014. It included the following statements:

> 'I fully understand that I am not able to mention or discuss specific diabetes treatments, including Novo Nordisk's treatments, at any point. Novo Nordisk is committed to maintaining high ethical standards and complying with industry and government regulatory requirements. Novo Nordisk is bound by the ABPI Code of Practice. As participant in the interview I understand that I must adhere to clause 22 [sic] of the ABPI Code of Practice which states: "statements must not be made for the purposes of encouraging members of the public to ask their health care professional to prescribe a specific prescription only medicine."'

The named patient did not mention a specific product but a formulation of medicine (once-daily injection). There were once-daily injectable therapies for diabetes available from many manufacturers. In

Novo Nordisk's view, the complainant had taken the quotation out of context. At the start of his interview, the named patient referred to going for long walks and eating healthily, both of which had a positive impact on his weight and hyperglycaemia. Novo Nordisk considered that this was a balanced interview when read as a whole and did not breach Clauses 26.1 or 26.2 of the Code.

Certification of patient testimonies

Novo Nordisk stated that, in line with recertifying materials every two years, the patient testimonies were undergoing review within Zinc when it received the complaint. However, as part of the investigation into the complaint it was discovered that the testimonies had been uploaded for examination rather than recertification. They were now recertified. Novo Nordisk provided a copy of the roadmap of review and certification from Zinc for the patient testimonies which were in the diabetes section.

Additional training was being undertaken by the individual to ensure the processes as per the company's Certification of Materials standard operating procedure (SOP) and the Code were followed.

In response to a request for further information, Novo Nordisk stated that the patient videos for three named diabetes patients were first certified on 24 October 2014. The patient video for another named patient was first certified on 21 November 2014. The date which appeared on the video for the named patient who had given the quotation above referred to the date of preparation which was 1 October 2014. Novo Nordisk provided copies of the Zinc certificates for all the patient videos from that time.

On 17 November 2016 the videos were next uploaded onto Zinc for review by a third party agency, and forwarded within Zinc to the first approver. Initially they went through examination only, as explained above. They were then certified on 1 December 2016, once the error was discovered.

'After the Menopause' booklet

Novo Nordisk stated that the booklet was recertified on 14 September 2016. A copy of the certificate was provided. Novo Nordisk submitted that as it had funded the booklet, it was responsible for the content. It was clear that the website was funded and produced by Novo Nordisk UK, and there was a clear statement on the booklet that it was produced with support from the company. Novo Nordisk thus denied a breach of Clause 9.10.

In summary, Novo Nordisk stated that it had ensured that information on its website was balanced and appropriate for the audiences who might access it. The company submitted that it had maintained high standards.

PANEL RULING

The Panel noted that although the complainant had accessed the health professional section of the corporate website, the patient section had much the same information on it including the patient pictures and videos.

The Panel noted that it had previously issued guidance that companies could illustrate their promotional material with relevant patient case studies but that everything which the company stated, or the patient stated, about the disease or response to treatment would be subject to the Code. The Panel considered that the same advice would be applicable to non-promotional material. In the Panel's view there was no reason not to use the patients' names on the corporate website provided that the company had their permission to do so. The Panel noted Novo Nordisk's submission that patients had provided the appropriate consent and in that regard the Panel considered that high standards had been maintained. No breach of Clause 9.1 was ruled.

The Panel noted that the section of the website which dealt with diabetes included, *inter alia*, a link to Novo Nordisk products and a separate link to a patient video gallery. One of the patients featured in the video gallery had type 2 diabetes; he stated 'my doctor prescribed me a once-daily injection and it's utterly transformed my life. I can walk for miles with the dogs, play football with the grandkids, and I feel great'. The Panel noted Novo Nordisk's submission that the quotation had been taken out of context. At the start of the interview, the named patient referred to going for long walks and eating healthily, both of which had a positive impact on his weight and hyperglycaemia. However, in the Panel's view the named patient implied that despite this change 14 years ago, it was only three years ago when the once-daily injection was prescribed, that his life was 'utterly transformed'. One of the once-daily injections that the patient could have been prescribed was Novo Nordisk's product Victoza (liraglutide), information about which was available via the link to Novo Nordisk's products, although other once-daily injections for type 2 diabetes were available. Nonetheless, the Panel considered that it was exaggerated to state that a medicine 'utterly transformed' a life with the implication that it alone enabled the patient to walk miles and play football with children. The Panel noted that Clause 26.2 required, *inter alia*, that information about prescription only medicines to the public must not raise unfounded hopes of successful treatment. The Panel further noted that the supplementary information to Clause 26.2 stated that the requirements of Clause 7 relating to information also applied to information to the public. Clause 7.2 stated, *inter alia*, that information must not be misleading either directly or indirectly or by implication, by distortion, exaggeration or undue emphasis; any information, claim or comparison must be capable of substantiation. Given that the patient video was available on the patient section of the website, the Panel ruled a breach of Clause 26.2. The Panel did not consider that the patient video constituted an advertisement for a prescription only medicine to the public and in that regard it ruled no breach of Clause 26.1.

The Panel noted that the patient videos had originally been certified in October or November 2014. The Code required material to be recertified every two years if it was to remain in use. The Panel noted Novo Nordisk's submission that although the case studies had been entered into Zinc on 17 November 2016, they had, at first, only been examined, not certified. They were finally recertified on 1 December 2016 ie more than two years after first being certified.

In that regard the Panel ruled a breach of Clause 14.5.

The Panel noted that the corporate website also featured a section on HRT. Within that section, readers could download a copy of a booklet entitled 'After the Menopause A personal guide for women'. On the front cover of the booklet the independent author's details were stated, below which was a statement that the booklet had been produced by Novo Nordisk. The Panel noted that Clause 9.10 required companies to clearly indicate their sponsorship of, *inter alia*, information relating to human health and diseases. The supplementary information stated that the wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. The Panel noted that Novo Nordisk had acknowledged that it was responsible for the content of the booklet. However, in the Panel's view the statement that the booklet had been 'Produced by Novo Nordisk' gave no indication as to the company's involvement, if any, in its content. The Panel ruled a breach of Clause 9.10.

The Panel noted that the date of preparation stated on the last page of the booklet was October 2014. Novo Nordisk had provided a certificate to show that the booklet was last re-certified in September 2016 - within two years of the previous certification. The Panel thus ruled no breach of Clause 14.5.

2 Professional resource website

COMPLAINT

The complainant noted that the resources available for health professionals to download from this website included several clinical papers. In the case of Victoza resources, this directed to a separate website to download the paper, whereas in the Xultophy (insulin degludec/liraglutide) section it did not. The complainant stated that although these papers were on a promotional website and were solely for the promoted products, there was no evidence that they had been reviewed to ensure that no material was off licence and there was no prescribing information on any of the items. It was therefore impossible to know when, and if, the articles were last reviewed.

RESPONSE

The clinical papers referred to by the complainant were on a website that users could access only after they had confirmed that they were health professionals. It was approved for use by UK health professionals only and was clearly identified as such; Novo Nordisk provided a screen shot of the landing page.

Novo Nordisk noted that the complainant had specifically referred to clinical papers which were available on the Victoza professional resources page and the Xultophy professional resources page. A link to the summary of product characteristics (SPC), and also a link to the prescribing information was clearly available on these pages. Therefore Novo Nordisk disagreed with the complainant's assertion that there was no prescribing information for the items, and that Novo Nordisk was in breach of Clauses 4.1 or 4.6. The papers would clearly be read within the context of those professional resource pages. They were not proactively supplied to a health professional, the health professional chose to click on them and read them.

The clinical papers were references used as part of the current marketing campaigns for both Victoza and Xultophy, therefore they were up-to-date and relevant, and did not cover unlicensed information.

In response to a request for further information, Novo Nordisk explained that health professionals were directed to the website via: the Novo Nordisk UK corporate website; promotional leavepieces given to health professionals to promote a brand, some of which included the website address for the health professional to visit if they wanted further information about the brand; promotional brand related e-mails. Promotional e-mails were sent as part of an e-mail campaign for different brands. If health professionals clicked for further information they were taken to the website and the diabetes representatives. The diabetes sales team was briefed with regard to videos in which health professionals discussed their experience with Xultophy. As part of that briefing they were told that one of the places the video could be accessed was the Novo Nordisk professional website. A copy of the briefing document was provided.

PANEL RULING

The Panel noted that the website was for health professionals only; they were directed to it as a professional resource via representatives and/or promotional material. Health professionals were also directed to the site via the corporate website. The complainant had drawn attention to clinical papers which, *inter alia*, were available to download from the website; the reprints were, according to Novo Nordisk's submission, the references used in the current marketing campaigns for Victoza and Xultophy. The Panel considered that upon visiting the website and possibly downloading the reprints, relevant prescribing information should, at the same time, be available to the health professional and in that regard it noted that prescribing information could be accessed via a separate but prominent link in the same screenshot as the reprints. No breach of Clause 4.1 was ruled. The link to the prescribing information was clear. No breach of Clause 4.6 was ruled.

During the consideration of this matter, the Panel noted that although the complainant had queried whether the clinical papers had been reviewed to ensure that no material was off licence, he/she had not made any specific complaint in that regard and Novo Nordisk had thus not been asked to consider the requirements of Clause 3.2. It was for the complainant to make out his/her case; he/she had the burden of proving his/her complaint on the balance of probabilities.

Complaint received **18 November 2016**

Case completed **4 April 2017**