GENERAL PRACTITIONER v NOVO NORDISK

Articles in Daily Mail

A general practitioner complained about articles in the Daily Mail which referred to liraglutide (Victoza) marketed by Novo Nordisk. Victoza was indicated for the treatment of adults with type 2 diabetes to achieve glycaemic control in combination with oral anti-hyperglycaemics.

The complainant alleged that in a Daily Mail online article the managing director of Novo Nordisk promoted liraglutide as a treatment for weight reduction, for which it was not licensed. His claims of phenomenal study results were exaggerated and disparaged orlistat, which was licensed as a weight loss agent. He also stated that liraglutide could cure diabetes and that its effects on confidence and health were life-changing!! Liraglutide was not a dieting medicine let alone an antihypertensive or lipid modifying agent as stated. The complainant alleged that this sort of irresponsible and disguised promotion only raised unfounded hopes.

The complainant also referred to a second article in which experts and opinion leaders, no doubt supported by Novo Nordisk, advocated or promoted liraglutide as a treatment for weight loss.

This was similar to previous rulings involving Novo Nordisk (Cases AUTH/2202/1/09 and AUTH/2234/5/09) and the complainant asked what was the point of the Authority ruling a breach of the Code including Clause 2 or imposing any other sanction on the company.

The detailed response from Novo Nordisk is given below.

The Panel noted that the complainant referred to an article published on 27 December 2010 in the Mail Online which described liraglutide as a diet drug that could be available in three years and as a jab that had produced phenomenal results. It was stated to be 'More than twice as good as anything on the market'. The article explained that liraglutide 'lowers blood pressure, raises "good" cholesterol and can prevent and even cure diabetes'. Its current use in diabetes was mentioned as was the ongoing trial programme in obese men and women. Comparative data with orlistat, a medicine licensed for weight loss, was discussed which appeared to have been taken from Astrup *et al* (2009) and which was provided to the Daily Mail journalist at her request. The Novo Nordisk managing director was quoted as stating 'We have had phenomenal results from the first clinical trials in obesity' and 'that the effects on confidence and health were life-changing'. The article also featured quotations from an academic expert in hormones and weight loss.

The Panel noted that Novo Nordisk's PR agency had developed a media programme to raise the profile of Novo Nordisk and strengthen its relationships with journalists. Meetings on varying topics had been arranged with individual journalists. In the Panel's view, the selection of such journalists should stand up to scrutiny; it might be unacceptable to select a journalist who had repeatedly published material related to the subject matter of a proposed meeting which was inconsistent with the Code. In its draft proposal for the media programme, Novo Nordisk's agent had listed as potential topics for discussion with the Daily Mail journalist, modern life with diabetes, how treatments were evolving to improve day-to-day lives of patients and the future of diabetes (pipeline).

The Panel noted that Novo Nordisk's agency had arranged a meeting with the journalist to discuss the human, social and financial impact of diabetes and Novo Nordisk's heritage with diabetes care. Slide 15 of the presentation delivered at the meeting described the company's range of rapid-acting, long-acting and pre-mixed insulin although no brand names were mentioned. The following slide was headed 'GLP-1 receptor agonist': whilst not mentioning liraglutide by name it was described as a treatment for type 2 diabetes as an adjunct to diet and exercise in combination with specified anti-diabetic tablets. Slide 17 headed 'Addressing future diabetes care needs' listed 'Next generation insulin analogues', 'Incretin therapies', 'Oral insulin and oral GLP-1' and 'A cure for Type 1 diabetes'. None of the slides mentioned obesity. The presentation concluded by a discussion of work undertaken by Novo Nordisk to change diabetes through partnerships, access and quality of life. Slide 22 detailed Novo Nordisk's impact on 6 quality of life parameters for people with diabetes: the second bullet point read 'Only company with a once-daily GLP-1 analogue'. The Panel queried whether, given the stated aim of the meeting, the presentation had included disproportionate emphasis on liraglutide.

The Panel noted that the meeting notes detailed a general discussion but did not appear to cover the presentation. The Panel had no way of knowing precisely what was said about the slides.

The meeting notes showed that the journalist knew a lot about liraglutide from the European Obesity Conference and had also written about it on publication of the recommendation from the National Institute for health and Clinical Excellence (NICE) [for its use in diabetes]. The journalist requested information on how liraglutide worked,

its mode of action and trials for obesity and timelines. The journalist was told she would be provided with a liraglutide backgrounder and published obesity trial results (Astrup *et al*). The journalist later asked about the timelines of getting liraglutide on the market for obesity and was told that a rough timeline might be three years. According to the meeting notes when the journalist referred to liraglutide and obesity the Novo Nordisk representatives steered the conversation back to the original topic. Although the Panel was concerned that liraglutide was the only specific medicine mentioned it did not appear from either the presentation or the meeting notes that the request about liraglutide and obesity was solicited by Novo Nordisk.

The Panel had some concerns about the arrangements, presentation and discussion as set out above. Nonetheless the Panel did not consider that, on the evidence before it, the presentation, discussion and material provided to the journalist promoted a prescription only medicine to the public as alleged. No breach of the Code was ruled. Nor, on balance, did the Panel consider that the material provided was not factual or balanced in relation to the licensed indication for liraglutide, nor did it otherwise encourage a member of the public to seek a prescription for it. Novo Nordisk did not proactively provide information on liraglutide and obesity. No breach of the Code was ruled.

The Panel noted the complainant's reference to Cases AUTH/2202/1/09 and AUTH/2234/5/09, wherein breaches of the Code had been ruled and additional sanctions imposed in relation to the pre-licence promotion of liraglutide and its promotion to the public. Turning to the present case, Case AUTH/2382/1/11, the Panel noted its rulings of no breach of the Code above and thus ruled no breach of the Code including Clause 2.

A general practitioner complained about articles in the Daily Mail which referred to liraglutide (Victoza) marketed by Novo Nordisk Limited. Victoza was indicated for the treatment of adults with type 2 diabetes to achieve glycaemic control in combination with oral anti-hyperglycaemics.

COMPLAINT

The complainant stated that he had read, with interest, the rulings of the Authority advertised in the December 2010 issue of the Pharmaceutical Journal and noted, in particular, the prominence of Novo Nordisk in this regard. However, it appeared that the sanctions applied by the Authority had not had any great impact on Novo Nordisk's ongoing activities when it came to promoting prescription medicines to the public.

On 19 January 2011, the complainant read an article in the Daily Mail online [http://www.dailymail.co.uk/health/article-1341818/Jab-help-drop-dress-sizes-months.html] in which the managing director of Novo Nordisk clearly promoted the use of liraglutide as a treatment for weight reduction, for which it was not licensed. His claims of phenomenal study results reported for liraglutide were exaggerated and disparaged orlistat, which was licensed as a weight loss agent, and went beyond the pale by stating that liraglutide could cure diabetes and that its effects on confidence and health were life-changing!! Liraglutide was not a dieting medicine let alone an antihypertensive or lipid modifying agent as stated. The complainant alleged that this sort of irresponsible and disguised promotion only served to raise unfounded hopes. It was clear that this article appeared in print during December 2010 and was one of several such articles.

The complainant noted a second article [http://www.dailymail.co.uk/home/search.html?searchPhrase=liraglutide] which involved so-called experts and opinion leaders, no doubt supported by Novo Nordisk, who advocated or promoted the off-licence use of liraglutide as a treatment for weight loss.

This all seemed reminiscent of previous rulings against Novo Nordisk (Cases AUTH/2202/1/09 and AUTH/2234/5/09) and the complainant asked what was the point of the Authority ruling a breach of Clauses 2 and 9.1 or any other clause, or imposing any other sanction on the company.

When writing to Novo Nordisk, the Authority asked it to respond in relation to Clauses 2, 9.1, 22.1 and 22.2 of the Code.

RESPONSE

Novo Nordisk stated that its communications team had recently embarked upon a series of meetings with key journalists in the consumer media to raise the profile of Novo Nordisk and the wider diabetes pandemic. It was hoped that following these meetings, journalists would write an article or articles on the issues surrounding diabetes in order to increase the public's awareness and understanding of diabetes. These meetings were not arranged to create a platform from which to promote Victoza or any other Novo Nordisk product to the public.

Novo Nordisk's media agency arranged a meeting between its managing director, a Daily Mail journalist and a member of the communications team to discuss the human, social and financial impact of diabetes in the UK and Novo Nordisk's heritage within diabetes care. This meeting took place on Thursday, 11 November 2010.

A certified slide deck was used as a conversation piece for the meeting. This included information on the Novo Nordisk strategy, the triple bottom line principles (balancing Novo Nordisk's financial return with social and environmental commitments) and the growing diabetes pandemic which provided some published and approved facts and figures. During the discussion, the journalist stated that she

knew quite a lot about liraglutide and that she had independently attended the European Obesity Conference. The journalist then asked about the clinical trials for the use of liraglutide in obesity and what information Novo Nordisk could share. Novo Nordisk agreed to send a written statement on the liraglutide obesity trials, but could not discuss it within the scope of the meeting. On a couple of occasions throughout the meeting, the journalist asked for this information and each time Novo Nordisk stated that it would send her the appropriate published information at a later date and then brought the meeting back to the subject of highlighting the impact of diabetes. This was detailed within the minutes of the meeting which were written by a member of the communications team. A redacted copy was provided.

At the close of the meeting, the journalist was told that if she were to write an article on diabetes or would like more information on current diabetes statistics, or a quotation from the company then she would be welcome to contact the communications team. Novo Nordisk also asked to review any quotations she intended to use before publication.

Following the meeting, the journalist emailed the member of the communications team who had attended the meeting to ask for information on the mode of action of Victoza. A certified document entitled 'Incretin Backgounder' was sent to the journalist on 23 November 2010. On receipt of this, the journalist asked for further information on the liraglutide/obesity trial programme. The communications team asked her to email her enquiry and Novo Nordisk responded on 2 December with a non-promotional statement and cited top line phase 2 clinical trial results that were publicly available. In the particular situation, a timely response was required and therefore the liraglutide/obesity information was approved by two signatories on email, rather than going through the company's normal approval route. This was in line with the standard operating procedure for the provision of information to journalists. The above two documents were provided in accordance with the supplementary information to Clause 22.2; both were factual and balanced and were not given to the journalist for the purpose of encouraging members of the public to ask their doctor or other prescriber about Victoza. Having reviewed the Daily Mail article, Novo Nordisk saw no correlation between the information it reactively provided to the journalist and the article itself.

Novo Nordisk was alerted to the journalist's online and paper article entitled 'Jab that could help you drop two dress sizes in six months', via its media monitoring service on 27 December 2010. Having read the articles, on return from the Christmas holidays it sent a rebuttal to the journalist as the information in the article was factually incorrect and Novo Nordisk had been misquoted. Within this email correspondence (sent Tuesday, 11 January) Novo Nordisk also reminded the journalist that it would have appreciated sight of any quotations before publication so that it could ensure it was factually accurate and a fair representation of any comments provided.

Within the article itself, Novo Nordisk's managing director was quoted as stating 'We have had phenomenal results from the first clinical trials in obesity' and that effects were 'life-changing'. Novo Nordisk noted that this was not what was said, and it had been misquoted in the article.

Novo Nordisk stated that neither it nor, to the best of its knowledge, information and belief, any other member of the Novo Nordisk group of companies outside the UK, issued any company announcement, press release or any other communication, in relation to the Daily Mail articles.

Novo Nordisk explained that a professor, a leading expert in the field of obesity who was referred to in the Daily Mail article, was an investigator for the company in the phase 2 clinical trial programme investigating liraglutide for the treatment of obesity. It was also planned that he would be involved in the phase 3 trial programme. In addition, he had been involved in global Novo Nordisk advisory boards in relation to these trial programmes, but had not been trained by Novo Nordisk, nor had he been asked by Novo Nordisk to speak with the media.

Novo Nordisk stated that neither it nor, to the best of its knowledge, information and belief, any other member of the Novo Nordisk group of companies outside the UK, engaged with the professor to provide quotations to the journalist for the Daily Mail articles.

The firm objective of the meeting with the journalist was to raise the awareness of diabetes with a health correspondent, using the slide deck discussed during the meeting. Two further documents were provided to the journalist after the meeting in accordance with the supplementary information to Clause 22.2 of the Code. In summary, Novo Nordisk did not use the meeting, nor did it use the provision of further information to the journalist after the meeting, to promote liraglutide as a treatment for obesity. Furthermore, the managing director was misquoted in the article for which a rebuttal was sent to the journalist. Novo Nordisk also understood that the journalist had independently educated herself in this matter and it was not Novo Nordisk that had driven her interest in this subject. Novo Nordisk therefore did not believe it had breached Clauses 2, 9.1, 22.1 or 22.2 of the Code.

In response to a request for further information Novo Nordisk explained that in early September 2010, it briefed its agency to provide a proposal for a media programme to raise the profile of Novo Nordisk and strengthen its relationships with journalists. The agency emailed a draft proposal on 17 September 2010, a copy of which was provided, which put forward a wide range of potential topics for discussion, including Novo Nordisk's commitment to changing diabetes. The

communications team met the agency on 28 September to discuss its provisional proposal.

In the event Novo Nordisk decided that while its agency would handle the logistics for any such media meetings, Novo Nordisk's managing director would be briefed in-house by Novo Nordisk. This led to the certified slide deck which Novo Nordisk's managing director used for the basis of his meeting with the journalist. It was never discussed within Novo Nordisk or with its agency that the meeting with the journalist would cover liraglutide and obesity.

The invitation to the journalist to meet Novo Nordisk was sent by Novo Nordisk's agency; a copy was provided. The Daily Mail was selected to take part in the programme as it was a key stakeholder in consumer press. The journalist, the science correspondent, was targeted specifically because Novo Nordisk's analysis had suggested that she had a particularly strong interest in writing about diabetes. The meeting with the journalist lasted one hour fifteen minutes. The journalist was not provided with a copy of the Victoza summary of product characteristics (SPC). Novo Nordisk reiterated that the journalist's contact with the professor was not facilitated by Novo Nordisk or one of its agents.

PANEL RULING

The Panel noted that Clause 22.1 prohibited the advertising of prescription only medicines to the public. Clause 22.2 permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their doctor to prescribe a specific product. Complaints about articles in the media were judged on the material provided by the company; such material should comply with the Code and in particular Clause 22.

The Panel noted that the complainant referred to an article published on 27 December 2010 in the Mail Online entitled 'Jab that could help you drop two dress sizes in six months'. Liraglutide was described as a diet drug that could be available in three years and as a jab that had produced phenomenal results. It was stated to be 'More than twice as good as anything on the market'. The article explained that liraglutide 'lowers blood pressure, raises "good" cholesterol and can prevent and even cure diabetes'. Its current use in diabetes was mentioned as was the ongoing trial programme in obese men and women. Comparative data with orlistat, a medicine licensed for weight loss, was discussed which appeared to have been taken from Astrup *et al* (2009) and which was provided to the Daily Mail journalist at her request. The Novo Nordisk managing director was quoted as stating 'We have had phenomenal results from the first clinical trials in obesity' and 'that the effects on confidence and health were life-changing'. The article also featured quotations from an academic expert in hormones and weight loss.

The Panel noted that Novo Nordisk's PR agency had developed a media programme designed to raise the profile of Novo Nordisk and strengthen its relationships with journalists. A series of meetings on varying topics had been arranged with individual journalists. In the Panel's view, the selection of such journalists should stand up to scrutiny; it might be unacceptable to select a journalist who had repeatedly published material related to the subject matter of a proposed meeting which was inconsistent with the Code. In its draft proposal for the media programme, Novo Nordisk's agent had listed as potential topics for discussion with the Daily Mail journalist, modern life with diabetes, how treatments were evolving to improve day-to-day lives of patients and the future of diabetes (pipeline).

The Panel noted that Novo Nordisk's agency had arranged a meeting with the journalist to discuss the human, social and financial impact of diabetes and Novo Nordisk's heritage with diabetes care. The presentation delivered at the meeting 'Changing the future of diabetes' discussed the incidence, human, social and economic consequences of diabetes. Slide 15 described the company's range of rapid-acting, long-acting and pre-mixed insulin although no brand names were mentioned. The following slide was headed 'GLP-1 receptor agonist': whilst not mentioning liraglutide by name it was described as a treatment for type 2 diabetes as an adjunct to diet and exercise in combination with specified anti-diabetic tablets. Slide 17 headed 'Addressing future diabetes care needs' listed 'Next generation insulin analogues', 'Incretin therapies', 'Oral insulin and oral GLP-1' and 'A cure for Type 1 diabetes'. None of the slides mentioned obesity. The presentation concluded by a discussion of work undertaken by Novo Nordisk to change diabetes through partnerships, access and quality of life. Slide 22 detailed Novo Nordisk's impact on six quality of life parameters for people with diabetes: the second bullet point read 'Only company with a once-daily GLP-1 analogue'. The Panel queried whether, given the stated aim of the meeting, the presentation had included disproportionate emphasis on liraglutide.

The Panel noted that the meeting notes detailed a general discussion but did not appear to cover the presentation. The Panel had no way of knowing precisely what was said about the slides.

The Panel noted that according to the meeting notes, the journalist explained that she knew a lot about liraglutide from the European Obesity Conference and had also written about it on publication of the recommendation from the National Institute for health and Clinical Excellence (NICE) [for its use in diabetes]. The journalist requested information on how liraglutide worked, its mode of action and trials for obesity and

timelines. The journalist was told she would be provided with a liraglutide backgrounder and published obesity trial results (Astrup *et al*). The journalist later asked about the timelines of getting liraglutide on the market for obesity and was told that a rough timeline might be three years. According to the meeting notes when the journalist referred to liraglutide and obesity the Novo Nordisk representatives steered the conversation back to the original topic. Although the Panel was concerned that liraglutide was the only specific medicine mentioned it did not appear from either the presentation slides or the meeting notes that the request about liraglutide and obesity was directly or indirectly solicited by Novo Nordisk.

The Panel had some concerns about the arrangements, presentation and discussion as set out above. Nonetheless the Panel did not consider that, on the evidence before it, the presentation, discussion and material provided to the journalist promoted a prescription only medicine to the public as alleged. No breach of Clause 22.1 was ruled. Nor, on balance, did the Panel consider that the material provided was not factual or balanced in relation to the licensed indication for liraglutide, nor did it otherwise encourage a member of the public to seek a prescription for it. Novo Nordisk did not proactively provide information on liraglutide and obesity. No breach of Clause 22.2 was ruled.

The Panel noted that the complainant had referred to Cases AUTH/2202/1/09 and AUTH/2234/5/09, wherein breaches of the Code had been ruled and additional sanctions imposed, as examples of Novo Nordisk's conduct in relation to the Code. The Panel noted that the cases cited concerned, *inter alia*, the pre-licence promotion of liraglutide and its promotion to the public. Turning to the present case, Case AUTH/2382/1/11, the Panel noted its rulings of no breach of the Code above and thus ruled no breach of Clause 9.1 and consequently, Clause 2.

Complaint received **19 January 2011**

Case completed **15 April 2011**