CASE AUTH/2202/1/09

LILLY v NOVO NORDISK

Diabetes supplement in The Times

Lilly alleged that an article 'Gut protein drug expected to help improve control' within a diabetes supplement distributed with The Times newspaper, constituted pre-licence promotion of liraglutide in breach of the Code. The article, based upon an interview with a senior executive of Novo Nordisk, referred to clinical trials of liraglutide which had demonstrated 'better blood glucose control …' and that it '… has also helped people reduce weight'.

Lilly did not consider that the supplement, which had been sponsored by Novo Nordisk and distributed to coincide with World Diabetes Day, was a reasonable forum to 'discuss future [unlicensed] therapies' as had been asserted by Novo Nordisk in inter-company dialogue.

The detailed response from Novo Nordisk is given below.

The Panel noted that the supplement at issue had been fully funded by Novo Nordisk which had full editorial control, owned the copyright and was part of the editorial team.

The article, 'Gut protein drug expected to help improve control' was the record of an interview by a journalist with Novo Nordisk's chief science officer. The Panel considered that the inclusion of this article showed that Novo Nordisk had contributed material about liraglutide and so in that regard had been able to influence the content of the supplement in a manner which favoured its interests. There was no strictly arm's length arrangement between the provision of sponsorship and the content of the supplement. The Panel thus considered that Novo Nordisk was responsible for the content of the supplement in relation to compliance with the Code.

In his interview, Novo Nordisk's chief science officer stated, *inter alia*, that clinical trials of liraglutide had shown that not only did people maintain better control of their blood glucose levels but that it also helped them to lose weight. The Panel did not accept that the supplement in The Times was an acceptable forum to publish the results of clinical trials as submitted by Novo Nordisk. The Panel considered that patients would read the article and see liraglutide, with its 'single daily injection' and 'better glucose control' as a possible improvement on their current therapy and thus be encouraged to ask their health professional to prescribe it. In this regard the Panel considered it irrelevant that the product was as yet unavailable to prescribe. A breach of the Code was ruled. The Panel further considered that the article promoted liraglutide to the public prior to the grant of a marketing authorization. High standards had not been maintained. Breaches of the Code were ruled.

The Panel considered that companies should take particular care when producing materials for the public. The Panel considered that in this regard Novo Nordisk had failed to exercise due diligence and thus brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Eli Lilly and Company Limited alleged that an article in a 16 page diabetes supplement, 'Changing the Future of Diabetes', which was distributed with The Times on 14 November, promoted Novo Nordisk Limited's product liraglutide prior to the grant of its marketing authorization. Inter-company dialogue had failed to resolve the matter.

COMPLAINT

Lilly alleged that the article, 'Gut protein drug expected to help improve control' constituted the pre-licence promotion of liraglutide to health professionals and the public and breached the Code.

On 14 November 2008 The Times newspaper and a media agency, in association with Novo Nordisk and other stakeholders, published the supplement entitled 'Changing the Future of Diabetes'. The article on page fourteen, 'Gut protein drug expected to help improve control' was based upon an interview with Novo Nordisk's chief science officer. The chief science officer explained the developmental hypothesis and putative mode of action of liraglutide, that its use involved a single daily injection and claimed that 'Clinical trials of liraglutide, have shown that people have better blood glucose control…'. The article also elaborated on the observation that liraglutide '… has also helped people reduce weight'. The article mentioned that liraglutide was currently unapproved in Europe and America; a fact corroborated by Novo Nordisk.

Further, in its response to Lilly's concerns, Novo Nordisk clearly acknowledged that the publication date for these pre-licence discussions of liraglutide was intended to coincide to 'mark World Diabetes Day' and 'to raise awareness of a wide variety of developments in the treatment of diabetes'. The latter was also evident in the interview with the managing director of Novo Nordisk UK & Ireland as reported on page three of the supplement. It was clear that Novo Nordisk was commercially motivated to use the opportunity afforded by the wide circulation of the supplement and the heightened awareness of diabetes, occasioned by a high-profile event such as

World Diabetes Day, to promote liraglutide. Indeed, Novo Nordisk had acknowledged that these pre-licence discussions were undertaken to disseminate information about Novo Nordisk products in development given the 'significant public and financial interests' in these.

Lilly did not accept the assertion that a publication sponsored by Novo Nordisk in The Times supplement was a reasonable forum to 'discuss future [unlicensed] therapies'. Given the latter, this was clearly a promotional publication, irrespective of the fallacious rationale proffered by Novo Nordisk regarding the 'context' in which the information regarding liraglutide appeared.

Lilly disagreed with Novo Nordisk's assertion that the provision of pre-licence information regarding liraglutide, to consumer journalists and its subsequent publication in consumer media constituted an educational activity. Equally concerning was the suggestion that the provision of information about liraglutide constituted 'raising awareness of the disease [diabetes]'. In this regard Lilly invited the Authority to consider that this activity was also in breach of the Medicines and Healthcare products Regulatory Agency (MHRA) Guidelines for Conducting Disease Awareness Campaigns.

Lilly was also concerned that Novo Nordisk appeared to rationalise its arguments in support of this pre-licence activity on the premise that Clauses 22.1 and 22.2 could not be applied to liraglutide 'as it cannot be prescribed', the premise for the latter being that 'liraglutide has not yet received a licence, [and therefore] it cannot be defined as a prescription only medicine'.

Lilly believed that the publication constituted the pre-licence promotion of liraglutide to the public, in breach of Clauses 9.1, 3.1, 22.1 and 22.2. Due to the serious nature of this matter and the obvious failing of Novo Nordisk to appreciate some of the most fundamental tenets of the Code, as evidenced by its response to Lilly of 4 December, Lilly also invited consideration of a breach of Clause 2.

RESPONSE

Novo Nordisk noted that the supplement contained a wide variety of articles, not specifically focusing on treatments or new drug development. As such, Novo Nordisk believed the publication of the article to coincide with World Diabetes Day, which was an International Diabetes Federation initiative to highlight diabetes, and was what the article was in support of, was valid and relevant, since the general impression of the publication was of raising the awareness of the disease, rather than specific company or product promotion. Novo Nordisk noted that Lilly had also referred to the interview with its managing director on page three of the supplement. However, Novo Nordisk understood that this section of the supplement did not constitute part of the complaint, and Novo Nordisk could not see any part of this section which corroborated the original complaint.

Novo Nordisk firmly believed that the supplement was an example of raising the profile of diabetes supported by Novo Nordisk amongst other stakeholders. With this in mind, Novo Nordisk believed the provision of information regarding clinical research (specifically, in the article in question, regarding liraglutide), complied with Clause 22. The article quite clearly stated that liraglutide '…is currently lodged with the relevant authorities in Europe and America' therefore positioning it as a future development rather than a current product that could be prescribed.

In addition to this, it was made very clear throughout the article that the stated effects of liraglutide were found as a result of clinical trials, and therefore Novo Nordisk considered the article constituted research findings. Indeed, Lilly had quoted from the article 'Clinical trials of liraglutide have shown that people have better blood glucose control'. The other quotation in this paragraph; '…has also helped people to reduce weight' should be taken in context, as the start of that particular sentence was 'In published clinical trials…'.

The argument raised by Lilly that this article was in breach of the MHRA Guidelines for Conducting Disease Awareness Campaigns depended on the view that the article made product-specific promotional claims. As Novo Nordisk had outlined above, it firmly believed that the mention of clinical research findings of a drug such as liraglutide was of interest, particularly when taken in context with other new and future developments also covered in the supplement.

In summary, Novo Nordisk considered that the article was a valid outline of the clinical research findings of liraglutide. The fact that the effects of the medicine related to clinical research was made very clear throughout the article, as was the fact that it was not yet approved. With this in mind, Novo Nordisk considered that it had complied with the Code and that it had not breached Clauses 9.1, 3.1, 22.1 22.2 or Clause 2.

Furthermore Novo Nordisk was committed to raising awareness of diabetes not only in the UK but also across the world. With more than 80 years' supporting diabetes Novo Nordisk spent off [sic] effort in this non product, non-promotional supplement where it, together with many diabetes stakeholders including patient organisations and health professionals, raised the awareness of diabetes and the importance of improving the treatment of diabetes, which was an example of one of Novo Nordisk's key values in line with its corporate social responsibility.

In response to a request for further information Novo Nordisk submitted that, for the third successive year, it, in association with its partners, sponsored the supplement which was published in The Times on World Diabetes Day. The main objective of the

supplement, as in previous years, was to inform, educate and promote diabetes care and management. In addition, it provided an opportunity for Novo Nordisk and its partners to communicate to all their relevant audiences how individually and collectively they were helping society tackle diabetes.

The media agency that managed the production of the supplement had a contract with The Times to distribute educational supplements with the paper. In the case of 'Changing the Future of Diabetes', the supplement was instigated by the agency and fully funded by Novo Nordisk. A copy of the sponsorship agreement between Novo Nordisk and the agency, dated 18 August 2008 was provided.

The supplement was written by a Times freelance journalist, and the review process was by committee between Novo Nordisk and all partners who contributed content. Novo Nordisk provided a list of co-sponsors. The authors were contacted directly by the journalist and Novo Nordisk checked the output for scientific accuracy for the Novo Nordisk contributors.

In addition to distribution with The Times on 14 November 2008, the clinical research group distributed approximately 80 copies on World Diabetes Day only; no copies were distributed by the sales and marketing teams. There were no plans for further dissemination.

PANEL RULING

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes. In the case of sponsored material aimed at the public consideration would also have to be given to the requirements of Clause 22.

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 prescription only medicine.

The supplement at issue had been fully funded by Novo Nordisk and was published to coincide with World Diabetes Day. The order confirmation between Novo Nordisk and the media agency that managed the publication of the supplement stated that Novo Nordisk had placed an order for sponsorship of the supplement. It further showed that Novo Nordisk had full editorial control, owned the copyright and was part of the editorial team. It appeared that the company had ordered 5,000 copies of the supplement; Novo Nordisk's clinical research group had distributed 80 copies on World Diabetes Day. The copy deadline was given as 31 October.

The article at issue, 'Gut protein drug expected to help improve control' was the record of an interview by a journalist with Novo Nordisk's chief science officer. The Panel considered that the inclusion of this article showed that Novo Nordisk had contributed material about liraglutide and so in that regard had been able to influence the content of the supplement in a manner which favoured its interests. There was no strictly arm's length arrangement between the provision of sponsorship and the content of the supplement. The Panel thus considered that Novo Nordisk was responsible for the content of the supplement in relation to compliance with the Code.

In his interview, Novo Nordisk's chief science officer referred to liraglutide stating that clinical trials of the product had shown that not only did people maintain better control of their blood glucose levels but that it also helped them to lose weight. The article stated that the medicine was currently lodged with the relevant authorities in Europe and the US and, if approved, would be expected to be available from mid 2009. The Panel did not accept that the supplement in The Times was an acceptable forum to publish the results of clinical trials as submitted by Novo Nordisk. The Panel considered that patients would read the article and see liraglutide, with its 'single daily injection' and 'better glucose control' as a possible improvement on their current therapy and thus be encouraged to ask their health professional to prescribe it. In this regard the Panel considered it irrelevant that the product was as yet unavailable to prescribe. A breach of Clause 22.2 was ruled. The Panel further considered that the article promoted liraglutide to the public. A breach of Clause 22.1 was ruled. Further, the product had, in effect, been promoted prior to the grant of a marketing authorization. A breach of Clause 3.1 was ruled. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel considered that companies should take particular care when producing materials for the public. The Panel considered that in this regard Novo Nordisk had failed to exercise due diligence and thus brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **23 January 2009**

Case completed **10 March 2009**