

# ANONYMOUS v NOVO NORDISK

## Invitation to a meeting

An anonymous, contactable complainant described as disturbing an email invitation to a Novo Nordisk satellite symposium entitled 'Weighing up the benefits: the practical use of GLP-1 [glucagon-like peptide-1] receptor agonists and modern insulins in tackling type 2 diabetes' due to be held at the Diabetes UK 2012 meeting. Two of the topics to be discussed would be individualisation of GLP-1 receptor agonist treatment and benefits of insulin analogues, focusing on hypoglycaemia. The invitation asked readers to register on-line and included a link to the Victoza (liraglutide) prescribing information.

Novo Nordisk marketed Victoza (a GLP-1 receptor agonist) as add-on therapy for adults with type 2 diabetes who had failed to achieve glycaemic control with oral antidiabetic therapy. Victoza was not licensed for use in combination with insulin. Novo Nordisk also marketed Levemir (insulin detemir) which had recently been granted a licence extension such that it could now be used in combination with Victoza.

The complainant noted that he/she had subscribed to a medical educational website from Novo Nordisk but not to promotional messages. The email at issue pointed to a symposium which promoted off label use of Victoza in combination with insulin (the linked prescribing information did not include a combination with insulin). The prescribing information for Novo Nordisk's insulins was not available to check. The website also only had prescribing information for Victoza so it was not clear that this was a promotional activity. The complainant noted that the registration website seemed open to everyone, not just doctors. The complainant did not consider that this was a legitimate activity.

The detailed response from Novo Nordisk is given below.

The Panel noted the complainant's submission that he/she had subscribed to a medical educational website but not to promotional messages. The homepage of the website stated that the site was for health professionals only and that they could obtain unlimited access to information, resources and tools about diabetes. The registration page of the website included the statement 'We would like to send you information about our products and services. I agree to be contacted by Novo Nordisk by post, telephone, email and SMS'. To the left of this was a box which was to be ticked to indicate agreement. The Panel noted that a request for permission to send promotional material had to be abundantly clear. The Panel did not consider that

this requirement had been met and thus a breach of the Code was ruled.

The Panel noted Novo Nordisk's submission that the symposium at issue did not discuss the use of liraglutide in combination with insulin. The invitation and agenda (which could be obtained via an electronic link in the invitation) showed that GLP-1 receptor agonists and insulin analogues (modern insulins) were to be discussed as two separate topics. The Panel noted that the complainant had not provided any evidence that the use of liraglutide in combination with insulin would be discussed at the symposium. No breach of the Code was ruled.

The Panel noted Novo Nordisk's submission that as it had only one GLP-1 receptor agonist, Victoza, the prescribing information was included. The Panel further noted Novo Nordisk's submission that it marketed three insulin analogues (Levemir, NovoRapid and NovoMix), but as the invitation did not refer to any by name, no prescribing information for any insulin was included. The Panel did not consider that the email promoted any particular insulin and thus no prescribing information for insulin was required. There was no disguised promotion of any insulin. No breaches of the Code were ruled. These rulings were upheld on appeal by the complainant.

The Panel noted the complainant's submission that the registration website appeared to be open access and not restricted to health professionals. The Panel noted Novo Nordisk's submission that the website was password protected and not accessible by the public. Health professionals who wished to access the site had to create an account by providing, *et al*, a professional registration number. Once registered a username and password were provided. The Panel noted that the registration page of the website, which anyone could access, contained no product or other clinical or promotional material. The Panel considered that in terms of access the website at issue complied with the Code. No breach of the Code was ruled. The Panel did not consider that the website promoted a prescription only medicine to the public and ruled no breach of the Code. These rulings were upheld on appeal by the complainant.

An anonymous, contactable complainant complained about an email invitation (ref UK/DB/0112/0028b) to a forthcoming Novo Nordisk satellite symposium entitled 'Weighing up the benefits: the practical use of GLP-1 [glucagon-like peptide-1] receptor agonists and modern insulins in tackling type 2 diabetes' which was to be held at the Diabetes UK 2012 meeting. The invitation stated that two of the topics to be discussed would be

individualisation of GLP-1 receptor agonist treatment and benefits of insulin analogues, focusing on hypoglycaemia. The invitation asked readers to register on-line. A link to the Victoza (liraglutide) prescribing information was included.

Novo Nordisk Limited marketed Victoza (a GLP-1 receptor agonist) as add-on therapy for adults with type 2 diabetes mellitus who had failed to achieve glycaemic control with oral antidiabetic therapy. Victoza was not licensed for use in combination with insulin. Novo Nordisk also marketed Levemir (insulin detemir) which had recently been granted a licence extension such that it could now be used in combination with Victoza.

## COMPLAINT

The complainant described the email as rather disturbing. He/she had subscribed to a medical educational website from Novo Nordisk ([novomedlink.co.uk](http://novomedlink.co.uk)) but not to promotional messages. The email at issue pointed to a symposium which promoted off label use of Victoza in combination with insulin (the complainant noted that the link to prescribing information at the bottom of the email did not include a combination with insulin). The complainant stated that Novo Nordisk also sold insulin but the prescribing information for these was not available to check. The website also only had prescribing information for Victoza so it was not clear that this was a promotional activity. The complainant noted that the registration website seemed open to everyone, not just doctors. The complainant did not consider that this was a legitimate activity.

When writing to Novo Nordisk, the Authority asked it to respond in relation to Clauses 3.2, 4.1, 9.9, 12.1, 22.1 and 24.1 of the Code.

## RESPONSE

Novo Nordisk explained that it owned and managed the website NovoMedLink which was an online resource for health professionals with an interest in diabetes. The website provided promotional and non-promotional information on all aspects of diabetes.

The website was password protected and was not accessible by the public. Health professionals who wished to access NovoMedLink had to create an account by providing standard personal details including a General Medical Council (GMC) number or nurse equivalent. Once registered, the health professional was given a username and password in order to access the site.

A screen print of the registration page of NovoMedLink was provided. Novo Nordisk submitted that this screen was displayed and completed when a health professional registered to the site. A section of the screen print was highlighted which Novo Nordisk stated clearly indicated that registered users who selected the tick box agreed to receive information on Novo Nordisk

products and services. This was also the case if a health professional registered to the site via a paper based system. Novo Nordisk submitted that as the complainant's details were unknown, it could not check whether he/she selected this box. However, the company was confident that it had a robust system to ensure that only users who had selected this box would receive such updates.

Novo Nordisk submitted that the invitation at issue was emailed on 24 February 2012 to all registered users of the NovoMedLink site who had agreed to receive such information upon registering with the website. A similar invitation was also distributed by hand to health professionals by the diabetes sales force.

Novo Nordisk stated that a link to the Victoza prescribing information was included on the invitation and the symposium registration website because the agenda referred to 'GLP-1 receptor agonists'. As Novo Nordisk only marketed one GLP-1 receptor agonist, Victoza could be identified. Prescribing information for the modern insulins had not been made available. Novo Nordisk submitted that it marketed several modern insulins, as did competitors, and there was no way to link the content of the symposium to a certain type of insulin. Since no specific insulin could be identified Novo Nordisk considered that there was no requirement for prescribing information for the modern insulins to be made available on the invitation or the symposium registration website.

Novo Nordisk submitted that its symposium at the Diabetes UK 2012 meeting was promotional. The three distinct topics which would be covered were GLP-1 receptor agonists, real life data and the importance of patient choice and the benefits of insulin analogues (modern insulins), focussing on hypoglycaemia.

Data around the use of combining liraglutide and a modern insulin as a treatment for diabetes were not discussed during this symposium. Novo Nordisk was therefore unclear as to why the complainant had alleged that the symposium would promote off label use of Victoza in combination with insulins but assumed that he/she might have misinterpreted the title of the symposium 'Weighing up the benefits: the practical use of GLP-1 receptor agonists and modern insulins in tackling type 2 diabetes'. As stated above, the agenda had been arranged to discuss GLP-1 receptor agonists and insulin analogues (modern insulins) in the treatment of diabetes as separate topics and not the use of GLP-1 receptor agonists in combination with modern insulins'.

Novo Nordisk noted, however, that its insulin analogue, Levemir recently received a licence update for add-on therapy to liraglutide treatment.

Novo Nordisk submitted that access to the symposium website was limited, as only health professionals who had received the invitation to the symposium via NovoMedLink or via a representative had been told about it. The registration website was

wholly directed to health professionals and the public had not been encouraged to access it.

Based on the above information, Novo Nordisk denied any breach of Clauses 22.1, 24.1, 12.1, 9.9, 4.1 or 3.2.

## PANEL RULING

The Panel noted the complainant's submission that he/she had subscribed to a medical educational website from Novo Nordisk, novomedlink.co.uk, but not to promotional messages. The homepage of the website stated that the site was for health professionals only and that they could obtain unlimited access to information, resources and tools about diabetes for them and their patients. The Panel noted that the registration page of the website had, below the registration details required, the statement 'We would like to send you information about our products and services. I agree to be contacted by Novo Nordisk by post, telephone, email and SMS'. There was a box to the left of this statement which was to be ticked to indicate agreement to this. The Panel noted that it had previously been established that text requesting permission to send promotional material had to make it abundantly clear that the intention was to send promotional material from pharmaceutical companies. The Panel did not consider that this requirement had been met in this case. A breach of Clause 9.9 was ruled.

The Panel noted Novo Nordisk's submission that the symposium at issue did not discuss the use of liraglutide in combination with insulin as a treatment for diabetes. The invitation and agenda, which could be obtained via an electronic link in the invitation, showed that GLP-1 receptor agonists and insulin analogues (modern insulins) in the treatment of diabetes were to be discussed as two separate topics ie 'Individualisation of GLP-1 receptor agonist treatment' and 'Benefits of insulin analogues, focusing on hypoglycaemia'. The Panel noted that the complainant had not provided any evidence that the use of liraglutide in combination with insulin would be discussed at the symposium. No breach of Clause 3.2 was ruled.

The Panel noted Novo Nordisk's submission that the email invitation to the symposium referred to GLP-1 receptor agonists and as Novo Nordisk marketed only one such medicine, Victoza, the prescribing information was included. The Panel further noted Novo Nordisk's submission that although it marketed three insulin analogues (Levemir, NovoRapid (insulin aspart) and NovoMix (biphasic insulin aspart)), the invitation did not refer to any by name and so it did not include prescribing information for any of its insulins. The Panel did not consider that the email promoted any particular insulin and thus no prescribing information for insulin was required. No breach of Clause 4.1 was ruled. There was no disguised promotion of any insulin, and no breach of Clause 12.1 was ruled. These rulings were appealed by the complainant.

The Panel noted the complainant's submission that the registration website appeared to be open access and not restricted to health professionals. The Panel noted Novo Nordisk's submission that the website was password protected and not accessible by the public. Health professionals who wished to access NovoMedLink had to create an account by providing standard personal details including a professional registration number. Once registered a username and password were provided so that a health professional could access the site. The Panel noted that the registration page of the website, which anyone could access, contained no product or other clinical or promotional material. The Panel considered that in terms of access the website at issue complied with the Code. No breach of Clause 24.1 was ruled. The Panel did not consider that the website promoted a prescription only medicine to the public and ruled no breach of Clause 22.1. These rulings were appealed by the complainant.

## APPEAL FROM THE COMPLAINANT

The complainant considered that there was some confusion as to his/her complaint about websites. The one he/she was not happy with was novonordisksymposium.com, which then redirected to the registration details for the symposium and the agenda and differed substantially from the email in that it had a lot more emphasis on liraglutide. This page was freely accessible; it was not an obscure link but one that might come up during searches. Indeed, it still popped up on a Google search. The complainant provided a screenshot and the last 'link' on that page was to the symposium. As the initial email displayed this link in large font the complainant queried whether Novo Nordisk wanted people to actively go to that site for future symposia. The link was designed to be easily remembered; in the complainant's view it should also be protected either by password or some form of registration. If Novo Nordisk really wanted it to be kept quiet, it should have stuck to the more obscure address which the site redirected to. That would have meant it would not be searchable on Google and would not encourage advertising to the public.

The complainant alleged that the description of the event on the email, with no mention of the medicine Novo Nordisk was overtly promoting, was misleading. The complainant expected the Victoza product logo to appear on the email so he/she would know whether or not to click on the link.

As for the lack of clarity of insulins, the complainant also did not accept the Panel's ruling. The title clearly referred to 'modern insulins'. Novo Nordisk blatantly meant its basal insulin [Levemir], the other products were more than ten years old. The mix version was just a combination of an old medicine. So Novo Nordisk was very clear that only modern insulins would be discussed. Being one of two, it was disingenuous of Novo Nordisk to pretend its product would not be discussed.

The complainant appealed the Panel's rulings of no breach of Clauses 4.1, 12.1 and 22.1.

The complainant further appealed the ruling of no breach of Clause 24.1 because the open access novonordisksymposium.com contained overtly promotional material.

## COMMENTS FROM NOVO NORDISK

Novo Nordisk disagreed that the agenda provided on the email invitation differed substantially to the agenda provided on the symposium registration website. The invitation provided recipients with an overview of the symposium so that they could decide whether they wanted to attend. The symposium registration website provided further detail on the agenda topics to be covered and was not inconsistent with the emailed agenda. Given the email invitation referred to GLP-1 receptor agonist treatment and contained a link to Victoza prescribing information, it was obvious that data regarding Victoza would be covered in the symposium.

Novo Nordisk reiterated that access to the symposium website was limited as only health professionals who were invited to the symposium via NovoMedLink or by a representative were told about it. The website was wholly directed to health professionals and the public was not encouraged to access it.

Novo Nordisk submitted that there had to be a deliberate search for the registration website using composite search criteria, ie linking Novo Nordisk with the scientific congress. Therefore Novo Nordisk disagreed that the site was 'freely accessible' and would pop up on a Google search.

Novo Nordisk submitted that it was self-evident that invitations to an event had to clearly inform delegates how they could register for the event if they wanted to attend. Highlighting the website address in large font on the email invitation was not unacceptable under the Code.

Novo Nordisk submitted that each symposium it organised had its own invitation detailing how to register for the event online, via a weblink. Novo Nordisk did not expect health professionals to register for a future meeting based on memories of an old invitation. The website in question was no longer available.

Novo Nordisk submitted that the email invitation clearly stated GLP-1 receptor agonist treatment was a key topic within the symposium. Novo Nordisk only marketed one such medicine and so Victoza could be identified; a link to the Victoza prescribing information was included on the invitation. Novo Nordisk did not believe there was a mandatory requirement to include a product logo on an invitation of this nature.

Novo Nordisk submitted that the email invitation clearly stated what Novo Nordisk paid for in relation to this symposium, and so it was clear that this was a Novo Nordisk organised promotional event and that GLP-1 receptor agonist treatment, including Victoza, would be discussed. Novo Nordisk therefore

disagreed that the agenda disguised the promotion of Victoza.

Novo Nordisk submitted that the complainant had stated that the only 'modern insulin' it marketed was a 'basal insulin'. In that regard Novo Nordisk explained that the term 'modern insulin' referred to all third generation insulins, ie all insulin analogues, and was very well recognised and regularly and widely used in the medical press and the electronic Medicines Compendium. As the terms 'modern insulins' and 'insulin analogues' could be used interchangeably both were referred to on the email invitation and the symposium registration website.

Novo Nordisk noted that it marketed three modern insulins, Levemir (basal insulin), NovoRapid and NovoMix. Novo Nordisk listed five other modern insulins marketed by other companies. Novo Nordisk therefore disagreed that 'modern insulin' only referred to its basal insulin.

Novo Nordisk submitted that, as previously stated, prescribing information for the modern insulins was not made available on the email invitation or the symposium registration website. As noted above, Novo Nordisk marketed several modern insulins, as did competitors, and the content of the symposium could not be linked to a certain type of insulin. Since no specific insulin could be identified Novo Nordisk submitted that there was no need for it to put the prescribing information for its modern insulins on the email invitation or the symposium registration website.

## FINAL COMMENTS FROM THE COMPLAINANT

The complainant considered that Novo Nordisk had denied the obvious. The complainant alleged that the agenda as set out in the email was substantially different to what was on the webpage. The agenda in the email read:

'Topics will include:

- Individualisation of GLP-1 receptor agonist treatment
- Real-life data and the importance of patient choice
- Benefits of insulin analogues, focusing on hypoglycaemia'

The complainant provided a copy of the subsequent confirmation email.

The complainant stated that the agenda on the web page, which he/she had to type because the page was now removed from the web, was as follows (emphasis added by the complainant and the quotation is from the complainant's version):

'Registration and refreshments  
Welcome and introduction  
Individualising patient care with GLP-1 receptor agonists  
**Liraglutide** in clinical practice  
**Liraglutide**: a patient's perspective  
What patients want



**The benefit of insulin analogues: clinical and economic impact of hypoglycaemia**  
Questions to the panel  
Summary and close.'

The complainant noted the marked difference between the agenda on the email and the website, with obvious emphasis on liraglutide. The complainant was not sure how Novo Nordisk considered this to be the same. The complainant noted that he/she received this email without the visit of a representative. Novo Nordisk stated that people who signed up to NovoMedLink were clear that they would receive promotional material. The Panel found this in breach. So, the fact that the email referred to an overtly promotional symposium was not made clear. The complainant submitted that he/she would not have clicked the link to find out more otherwise. It was an unbranded invitation at a major conference and the complainant expected a proper medical, balanced presentation with talks that dealt with all GLP-1s. The complainant noted that Novo Nordisk maintained that the mention of GLP-1 receptor agonist would imply Victoza but when it came to insulins, it did not make the same link.

The complainant alleged that the website was freely accessible to the public and that other health professional websites he/she visited either confirmed doctor/nurse status or asked for a GMC number etc. This would have solved the problem.

The complainant queried why the link to the website was in such large font. Why else would it be highlighted? It was obviously meant to remind readers to visit the page again. All the more reason to protect the access.

The complainant noted that, at first glance, the initial email only had the corporate livery, used broad terms and gave the impression of a scientific symposium. Instead, the agenda was highly focused only on Victoza. Why not use the Victoza logo? This was disguised promotion. Doctors should not have to look for a link to prescribing information to determine that something was promotional. It should be abundantly clear at first glance.

The complainant noted that Novo Nordisk had stated that it was addressing modern insulins and that the fact that it was not the only one on the market dispensed it from having to show prescribing information. The complainant disagreed; by its own admission, Novo Nordisk sold three of the eight modern insulins available.

The complainant continued to believe that Novo Nordisk had referred to its basal insulin. This was evident from the topic chosen 'The benefit of insulin analogues: clinical and economic impact of hypoglycaemia'. The hypoglycaemia benefit was a particular feature of basal insulins, not the other types. The complainant was annoyed that Novo Nordisk insisted that it had referred to eight insulin types, when it had obviously concentrated on basal insulins. So again, the omission of the Levemir logo

and prescribing information was disguised promotion.

In summary, the complainant alleged that Novo Nordisk should have been much more transparent in its mass email to signed up NovoMedLink doctors (a breach of Clause 9.9 had been accepted) when promoting its symposium and that the email should have clearly referred to the emphasis on Victoza and Levemir with the logos of each clearly displayed.

## **APPEAL BOARD RULING**

The Appeal Board noted that health professionals could sign up to novomedlink.co.uk to receive emails such as that received by the complainant. The Appeal Board noted from the representatives at the appeal that the purpose of the email was to provide 'top line' details on the symposium; if interested, the recipient could then follow the link at the end of the email to a separate registration website that provided a more detailed agenda and an option to register for the event. Novo Nordisk's sales representatives also provided health professionals who had not signed up to the website with the registration website details.

The Appeal Board noted that the invitation email had included the Novo Nordisk company logo indicating that Novo Nordisk had sponsored the symposium. The email referred to GLP-1 receptor agonists and as Novo Nordisk only marketed one of these, Victoza, the prescribing information was provided via a hyperlink. The Appeal Board noted that the email also mentioned modern insulins. As Novo Nordisk produced three insulin analogues (Levemir, NovoRapid and NovoMix) of the available eight and no particular insulin was identified, no prescribing information for any was provided. On the registration page, which also included the company logo, the agenda referred to liraglutide, and the prescribing information was again provided. Insulins were discussed but as none were identifiable no prescribing information was provided.

The Appeal Board considered that neither the email nor the registration page promoted any particular insulin and thus no prescribing information was required. The Appeal Board upheld the Panel's ruling of no breach of Clause 4.1. There was no disguised promotion of any insulin and from the initial email it was also clear that Novo Nordisk's GLP-1 receptor agonist, liraglutide, would be discussed. The Appeal Board upheld the Panel's ruling of no breach of Clause 12.1. The appeal on both points was unsuccessful.

The Appeal Board noted that by entering the correct combination in a composite Google search, the registration website could be returned. The Appeal Board considered that it was unfortunate that the registration website could be accessed by using only three search terms but considered that the likelihood of a member of the public accessing the registration website by this method was very low. Although it would have been preferable in this regard to manage

registration through novomedlink.co.uk directly, the Appeal Board considered that Novo Nordisk had taken reasonable steps. It did not consider that in this regard Novo Nordisk had promoted a prescription only medicine to the public. The Appeal Board upheld the Panel's ruling of no breach of Clause 22.1. The Appeal Board considered that in relation to access, the website complied with the Code and it upheld the Panel's ruling of no breach of Clause 24.1. The appeal on both points was unsuccessful.

**Complaint received**      **25 February 2012**

**Case completed**          **24 May 2012**

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