

**CASE AUTH/3445/12/20**

## **COMPLAINANT v NOVO NORDISK**

### **Promotion of Ozempic**

**A contactable complainant who described him/herself as a concerned health professional complained about a promotional email (ref UK20OZM00311) for Ozempic (semaglutide solution for injection) sent by Novo Nordisk Limited. Ozempic was indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, either as monotherapy or in combination with other medicines.**

**The complainant noted that the email detailed the results from the SUSTAIN 7 trial but did not state that one of the inclusion criteria was that patients had to be over the age of 18 years. Only further down and in much smaller writing did the email clarify that the treatment was only for adults, not all type 2 diabetes patients. The complainant submitted that type 2 diabetes was increasingly common in teenagers and so this was a serious omission. The complainant alleged that Ozempic had been promoted off licence.**

**The detailed response from Novo Nordisk is given below.**

**The Panel noted that the email at issue included ‘Could Ozempic help in the management of your patients with type 2 diabetes?’ followed by the claim ‘Ozempic has proven efficacy in decreasing HbA1c and could help your patients to reach their targets’. This was followed by information about the SUSTAIN 7 clinical trials and an invitation for the reader to ‘Learn more about the efficacy and tolerability of Ozempic for your patients with type 2 diabetes’. Beneath this, in smaller less prominent font, was the Ozempic indication followed by another link to prescribing information and adverse event reporting.**

**The Panel noted that the full indication for Ozempic, stating that it was licensed for the treatment of adults with type 2 diabetes, was towards the end of the email, after the information about SUSTAIN 7. The Panel noted Novo Nordisk’s submission that there was no suggestion within the email that Ozempic should be used in patients under 18 years of age. In the Panel’s view, it would be unusual for a patient with type 2 diabetes to be under 18 years old. Health professionals would take particular care when prescribing for such patients.**

**The Panel considered the immediate and overall impression to a busy health professional. There was no specific mention in the email or impression given that the email related to patients with type 2 diabetes who were under 18 years old. In the Panel’s view, although it might have been helpful for the indication to have been nearer the**

**beginning of the email, the email overall was not misleading in relation to the licensed indication as alleged and the Panel ruled no breaches of the Code including Clause 2.**

A contactable complainant who described him/herself as a concerned health professional complained about a promotional email (ref UK20OZM00311) for Ozempic (semaglutide solution for injection) sent by Novo Nordisk Limited via Pulse. Ozempic was indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, either as monotherapy or in combination with other medicines.

## **COMPLAINT**

The complainant noted that the email detailed the results from the SUSTAIN 7 trial but did not state that one of the inclusion criteria was that patients had to be over the age of 18 years. Only further down and in much smaller writing did the email clarify that the treatment was only for adults, not all type 2 diabetes patients. The complainant submitted that type 2 diabetes was increasingly common in teenagers and so this was a serious omission. The complainant alleged that Ozempic had been promoted off licence.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 7.2 and 9.1 of the Code.

## **RESPONSE**

Novo Nordisk categorically refuted that it had breached the Code; the full indication for Ozempic, stating that it was licensed for the treatment of adults with type 2 diabetes, was clearly stated within the body of the email:

‘Ozempic is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications in addition to other medicinal products for the treatment of diabetes.’

There was a prominent link to the prescribing information at the top of the email, which contained the full indication:

‘Ozempic is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin was considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.’

In addition, within the body of the email, there were links to an Ozempic promotional website. This was accessed when clicking on the headings highlighted in orange. Again, the full indication for Ozempic was prominent at the top of each page of the website.

Novo Nordisk submitted that the email was certified as a promotional mailing; its intent was to remind primary care health professionals about the recently published Royal College of General Practitioner’s (RCGP) guidance which outlined workload prioritisation during the Covid-19 pandemic as well as promoting Ozempic. The guidance recommended that patients with type 2 diabetes with HbA1c levels >75 mmol/mol should be prioritised for review during the Covid-19

pandemic. The email highlighted how Ozempic could help primary care clinicians manage adults with type 2 diabetes and high HbA1c levels. The messaging specifically focused on the ability for Ozempic to reduce HbA1c (Pratley *et al.* 2018a) and included data from a relevant *post-hoc* analysis of patients with a baseline HbA1c >75mmol/mol (Pratley *et al.* 2018b).

Novo Nordisk stated that the email was sent on 7 December 2020 to 17,372 general practitioners who were registered with Pulse Today. Identical emails were also sent on 12 November 2020 to 7,047 GPs who had signed up to promotional emails from doctors.net.uk (ref UK20OZM00115), and on 10 December 2020 to 13,153 nurses who had signed up to promotional emails via Nursing in Practice (ref UK20OZM00312). Novo Nordisk provided a copy of the emails and their certificates.

Novo Nordisk stated that the recipients had registered with Pulse, Nursing in Practice or doctors.net.uk to receive promotional emails from third parties. Cogora, a healthcare marketing agency which owned Pulse and Nursing in Practice, sent the emails to health professionals registered with those two sites. When registering with Pulse Today, Nursing in Practice and doctors.net.uk, subscribers had to confirm that they were health professionals. They were asked to opt-in to the emails they wished to receive. The registration process for each website asked users to confirm whether they wished to opt-in to receiving electronic marketing content, which might contain promotional material including from pharmaceutical companies, and details of how to unsubscribe. Novo Nordisk provided copies of the details of the registration process for health professionals registered with the respective websites to receive promotional emails from third parties.

Whilst the website was not the subject of the complaint, Novo Nordisk provided a pdf copy of the page which was directly accessed by clicking the links within the email. Novo Nordisk would provide further details about the website if required.

Novo Nordisk stated that all claims were consistent with the Ozempic summary of product characteristics (SPC). There was no suggestion that Ozempic should be used in patients under 18 years old. As stated above, the data presented from the SUSTAIN 7 trial in the email showed the results of the primary endpoint and the *post-hoc* analysis, only to show the evidence in reducing high HbA1c levels rather than giving full details of the study such as inclusion and exclusion criteria.

In conclusion, Novo Nordisk categorically denied that it had promoted the use of Ozempic in teenagers. The indication was clearly stated on the email, could be accessed via the prescribing information and was also stated on the website multiple times. The information within the email was not misleading and it did not encourage off-label use. Novo Nordisk denied breaches of Clauses 7.2, 9.1 and 2.

## **PANEL RULING**

The Panel noted that the subject line of the promotional email at issue stated: 'Promotional information from Novo Nordisk. Diabetes management during the COVID-19 pandemic'. The body of the email included the statement 'Promotional information from Novo Nordisk' at the top, beneath which was a link to prescribing information and adverse event reporting and this was followed by the Ozempic logo. Beneath this logo were the prominent statements: 'The RCGP recommends that patients with type 2 diabetes are prioritised during the pandemic' and 'Now, more than ever, we need to ensure that patients with type 2 diabetes are well managed',

followed by information regarding the RCGP guidance. Beneath this, in a hyperlinked orange box, it stated 'Could Ozempic help in the management of your patients with type 2 diabetes?' followed by the claim 'Ozempic has proven efficacy in decreasing HbA1c and could help your patients to reach their targets', as noted by the complainant. This was followed by information about the SUSTAIN 7 clinical trials and an invitation for the reader to 'Learn more about the efficacy and tolerability of Ozempic for your patients with type 2 diabetes'. Beneath this, in smaller less prominent font, was the Ozempic indication followed by another link to prescribing information and adverse event reporting.

The Panel noted that the full indication for Ozempic, stating that it was licensed for the treatment of adults with type 2 diabetes, was towards the end of the email, after the information about SUSTAIN 7. The Panel noted Novo Nordisk's submission that there was no suggestion within the email that Ozempic should be used in patients under 18 years of age. In the Panel's view, it would be unusual for a patient with type 2 diabetes to be under 18 years old. Health professionals would take particular care when prescribing for such patients.

Clause 7.2 stated, *inter alia*, that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

The Panel considered the immediate and overall impression to a busy health professional. There was no specific mention in the email or impression given that the email related to patients with type 2 diabetes who were under 18 years old. In the Panel's view, although it might have been helpful for the indication to have been nearer the beginning of the email, the email overall was not misleading in relation to the licensed indication as alleged and the Panel ruled no breach of Clause 7.2.

The Panel noted its comments and ruling above and consequently ruled no breach of Clauses 9.1 and Clause 2.

**Complaint received**      **19 December 2020**

**Case completed**        **14 June 2021**