CASE AUTH/3640/5/22

VOLUNTARY ADMISSION BY NOVO NORDISK

GLP-1 receptor agonist supply issue email (UKOZM00010)

CASE SUMMARY

This voluntary admission by Novo Nordisk was in relation to an email sent to health professionals to advise them that Novo Nordisk UK had no issues with the supply of the GLP-1 receptor agonists (GLP-1 RAs) Ozempic (semaglutide) and Rybelsus (semaglutide).

The Panel ruled a breach of the following Clause(s) of the 2021 Code as two representatives had each sent out the promotional email without all of the obligatory information being included:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.1	**Failing to include up-to-date prescribing information**
Breach of Clause 12.8	**Failing to include the date on which the promotional material was created or last revised**
Breach of Clause 12.9	**Failing to include information about how to report adverse events**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

Novo Nordisk made a voluntary admission about a GLP-1 receptor agonist supply issue email (ref UK22IOZM00010).

Novo Nordisk stated that it had come to its attention that the email was sent to health professionals without certain obligatory information being included. Novo Nordisk took self-regulation very seriously and as a result of identifying the above issue, it self-reported the matter.

VOLUNTARY ADMISSION

Novo Nordisk explained that the email was created to advise health professionals that Novo Nordisk UK had no issues with the supply of Ozempic (semaglutide) or Rybelsus (semaglutide) which were GLP-1 receptor agonists (GLP-1 RAs). The email template was certified as a promotional item and provided to diabetes sales representatives to email to health professionals both reactively and proactively. The email was certified by a medical signatory and approved for distribution in February 2022. The certified version included all required obligatory information. Representatives were instructed not to alter the email template in any way prior to sending, save for including the recipient's name and their own name as the sender.

It was identified in March 2022 that two representatives who utilised the email template inadvertently sent it without all required obligatory information included:

Representative 1
The email was sent to 95 health professionals and did not include the following information:

- Unique reference number.
- Date of preparation.
- Working hyperlinks to access digital versions of the Ozempic and Rybelsus prescribing information.
- Adverse event reporting box.

Representative 2
The email was sent to 8 health professionals and did not include the following information:

- Unique reference number.
- Date of preparation.
- Adverse event reporting box as shown in the body of the certified email template, although the adverse event reporting statement was included in the Ozempic and Rybelsus prescribing information made available via the hyperlinks within the email.

As a result, Novo Nordisk considered the following clauses had not been adhered to:

12.1: Provision of Prescribing Information.
12.8: Provision of date of preparation.
12.9: Provision of adverse event reporting information.

Novo Nordisk noted that the requirement to include a unique reference was referred to in the 2021 Guidelines on Company Procedures Relating to the Code.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 12.1, 12.8, 12.9 and in addition Clause 5.1 of the 2021 Code.

RESPONSE

Novo Nordisk stated that it had no further comments to add to the matter in relation to the clauses cited in its original letter, namely Clauses 12.1, 12.8 and 12.9 of the Code.

Novo Nordisk stated that in relation to a request to comment on Clause 5.1, Novo Nordisk stated that it did not consider it was in breach of this clause. Email UK22OZM00010 included all required obligatory information at the point of certification. This demonstrated that there was no deliberate attempt by Novo Nordisk to omit this information from the email template.

PANEL RULING

The Panel noted that whilst the inclusion of a unique reference number on material which corresponded to the same reference number on the certificate to identify what had been certified was referred to in the 2021 Guidelines on Company Procedures Relating to the ABPI Code of Practice for the Pharmaceutical Industry, it was not a requirement of the Code.

The Panel noted that the email in question had been sent by representative 1 to 95 health professionals without the date of preparation, adverse event statement and working hyperlinks to the Ozempic and Rybelsus prescribing information. The Panel therefore ruled **breaches of Clauses 12.8, 12.9 and 12.1** as acknowledged by Novo Nordisk.

The Panel noted that the email in question had been sent by representative 2 to 8 health professionals without the date of preparation and a **breach of Clause 12.8** was ruled as acknowledged by Novo Nordisk.

Whilst the Panel noted Novo Nordisk's submission that the adverse event reporting statement was included in the Ozempic and Rybelsus prescribing information made available via the hyperlinks within the email sent by representative 2, it noted that the statement did not appear within the email itself as required by Clause 12.9 and a **breach of Clause 12.9** was ruled.

The Panel noted its rulings of breaches of Clauses 12.8, 12.1 and 12.9 and considered that high standards had not been maintained; the email had been amended by both representatives following certification to remove important obligatory information and a **breach of Clause 5.1** was ruled.

Complaint received **1 May 2022**

Case completed **21 March 2023**