CASE AUTH/3653/5/22

ELI LILLY v NOVO NORDISK

Novo Nordisk position statement regarding supplies of certain Lilly medicines for diabetes

CASE SUMMARY

This case was in relation to promotional emails sent by Novo Nordisk Ltd to health professionals regarding the available supply of GLP-1 Receptor Agonists (GLP-1RAs).

The Panel ruled a breach of the following Clause of the 2021 Code as it considered that including the statement 'Novo Nordisk's priority is maintaining supply of treatment to support adults living with type 2 diabetes' followed by 'We can reassure you as an HCP, that we have supply available of all doses of both Ozempic® ▼ (once-weekly semaglutide) and RYBELSUS® ▼ (semaglutide tablets), should you be seeking a GLP-1 RA to prescribe for adults with type 2 diabetes at this time' directly below reference to Eli Lilly having supply issues was such that it implied that maintaining supply of treatment was not a priority for Eli Lilly and thus was disparaging towards Eli Lilly:

Breach of Clause 6.6	**Disparaging another company**

The Panel ruled no breach of the following Clauses of the 2021 Code based on the complainant's allegations because it did not consider that the emails misled the reader regarding the content of the referenced email from the Department of Health and Social Care (DHSC) to Novo Nordisk in relation to the timeframe of the stock outage of Lilly's product or misrepresented the DHSC's intentions by not making clear that switching to a Novo Nordisk GLP-1 RA was not the preferred option, nor did the Panel consider that the emails were in conflict with DHSC guidance with regards to when switching to an alternative GLP-1 RA should be considered, nor that referring to Rybelsus and not Bydureon and Victoza or continuing to reference a DHSC email rather than the official DHSC Medicine Supply Notification (MSN) was inappropriate and misleading as alleged:

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**

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

FULL CASE REPORT

Eli Lilly and Company Limited complained about emails sent by Novo Nordisk Ltd having failed to resolve the matter during inter-company dialogue.

COMPLAINT

Lilly believed that the promotional emails sent by Novo Nordisk to health professionals (copies provided) lacked obligatory information, disparaged Eli Lilly, and misled the reader regarding Department of Health and Social Care (DHSC) guidance in breach of Clauses 12.8, 12.9, 6.6, 5.1 (x2) and 2 of the 2021 Code. Regarding the promotional emails lacking the following, (1) a date of preparation in breach of Clause 12.8; (2) a statement regarding adverse event reporting, in breach of Clause 12.9; and (3) a unique reference number as required by the 2021 Guidelines on Company Procedures Relating to the ABPI Code of Practice for the Pharmaceutical Industry, representing a failure to maintain high standards in breach of Clause 5.1; Novo Nordisk had undertaken to self-report these aspects of the matter to the PMCPA.

Eli Lilly confirmed that its complaint outlined here was therefore confined to alleged breaches of Clauses 6.6, 5.1 and 2 of the 2021 ABPI Code of Practice.

BACKGROUND

Lilly explained that it experienced a temporary stock outage of the two higher doses (3.0 mg and 4.5 mg weekly) of Trulicity (dulaglutide), a GLP-1 receptor agonist (GLP-1 RA) indicated for the treatment of type 2 diabetes. The starting doses of 0.75 mg (monotherapy) and 1.5 mg (add-on therapy) were unaffected.

For context, the posology section of the Trulicity SmPC read:

> Posology
>
> *Monotherapy*
> The recommended dose is 0.75 mg once weekly.
> *Add-on therapy*
> The recommended dose is 1.5 mg once weekly.
> For potentially vulnerable populations 0.75 mg once weekly can be considered as a starting dose.
>
> For additional glycaemic control,
> - the 1.5 mg dose may be increased after at least 4 weeks to 3 mg once weekly.
> - the 3 mg dose may be increased after at least 4 weeks to 4.5 mg once weekly.

Lilly stated that it had a series of meetings with the DHSC, where Lilly notified them of the stock outage and discussed both its and Lilly's approaches to notification of health professionals. The DHSC indicated that they would be issuing a Medicine Supply Notification (MSN) in which they would be recommending 3 possible courses of action:

1 Temporary reversion of patients on the higher doses of dulaglutide to the 1.5 mg dose.
2 Switching to alternative GLP-1 RAs, with appropriate clinical considerations.
3 Temporary (off-label) use of multiple doses of 1.5 mg to make up the appropriate higher dose.

The MSN was issued on 10 February 2022 (copy provided).

In response to the stock outage of the higher doses of dulaglutide, Novo Nordisk issued promotional emails, variously titled 'Novo Nordisk Position Statement: GLP1-RA Supply Available' and 'GLP-1 Supply Available'. The former was sent before publication of the MSN and the latter after. Lilly had redacted the emails so that the health professionals could not be identified by either name or the date that the emails were sent.

In its response dated 16 March 2022, to the intercompany dialogue initiated by Lilly, Novo Nordisk stated that the emails were simply a response to queries related to the availability of Novo Nordisk GLP-1 RAs and were 'a measured, factually accurate email to reassure HCPs that we have no stock-out issues in relation to the supply of Ozempic and Rybelsus'.

Lilly found this to be completely implausible. Such an email would simply have read, 'We are writing in response to queries, to confirm that we have no stock-out issues with supply of our GLP-1 Ras'.

- The first paragraph in the promotional emails stated, 'Lilly have issued a notification via multiple sources that there is a temporary supply issue with two doses of Trulicity (dulaglutide), namely the 3.0 mg and 4.5 mg dose pens, affecting the availability of these two doses to healthcare professionals (HCPs) and patients in the UK.' In a measured email in response to queries from health professionals related to the availability of Novo Nordisk GLP-1 RAs, it would not have been necessary to include any mention of stock-out issues with the 3.0 mg and 4.5 mg doses of dulaglutide. The context would have been provided by stating that Novo Nordisk was writing in response to queries.
- In a measured email in response to queries from health professionals related to the availability of Novo Nordisk GLP-1 RAs, it would not have been appropriate to mention only Ozempic and Rybelsus. The promotional emails failed to mention Novo Nordisk's third commercially available GLP-1 RA, Victoza, for which they presumably did not have a stock-out issue. It was clear from Novo Nordisk's marketing campaigns that they were actively promoting Ozempic and Rybelsus, but not Victoza, although Victoza was commercially available and still used by, and initiated in, many patients. The fact that they were silent about availability of Victoza supported Lilly's belief that this was not a measured email in response to queries from health professionals related to the availability of Novo Nordisk GLP-1 RAs.
- In a measured email in response to queries from health professionals related to the availability of Novo Nordisk GLP-1 RAs, it would not have been necessary to include promotion of support materials for Ozempic and Rybelsus. The promotional emails referred to availability of the Ozempic app with device demonstration videos, the Ozempic dosing guide leave piece, and the RYBELSUS dosing guide.
- In a measured email in response to queries from health professionals related to the availability of Novo Nordisk GLP-1 RAs, it would not have been necessary to reference the DHSC.

Lilly stated that it believed that the most plausible interpretation of the promotional emails was that they were a cynical attempt to take commercial advantage of the temporary stock outage of the dulaglutide higher doses by implicitly suggesting a switch from dulaglutide higher doses to Ozempic or Rybelsus. The fact that the emails did not specifically use the word 'switching' was

irrelevant given the overall context. A prominent subheading in the emails, which began with a reference to the dulaglutide higher dose stock outage, read, 'If you are considering initiating a patient on GLP-1 RA therapy' and was followed by reassurance about availability of Ozempic and Rybelsus (with no mention of Victoza) and promotion of support materials for Ozempic and Rybelsus. Raising initiation of Ozempic or Rybelsus in a message that begins with reference to a stock outage of the Trulicity 3.0 mg and 4.5 mg doses clearly could not be referring to patients who are naïve to a GLP-1 RA as there was no stock outage of the two starting doses of Trulicity of 0.75 mg (monotherapy) and 1.5 mg (add-on therapy). Given the overall context therefore, the only rational interpretation by the reader was that Novo Nordisk was suggesting a switch from dulaglutide higher doses to Ozempic or Rybelsus.

LILLY SPECIFIC CODE-RELATED CONCERNS WITH THE PROMOTIONAL EMAILS

Disparagement of Eli Lilly in breach of Clause 6.6.

In the Novo Nordisk promotional emails, it was stated:

> Lilly ha*ve issued a notification via multiple sources that there is a temporary supply issue with two doses of Trulicity® (dulaglutide), namely the 3.0 mg and 4.5 mg dose pens, affecting the availability of these two doses to healthcare professionals (HCPs) and patients in the UK.*[1]
>
> *If you are considering initiating a patient on GLP-1 RA therapy:*
> - *Novo Nordisk's priority is maintaining supply of treatment to support adults living with type 2 diabetes*
> - *We can reassure you as an HCP, that we have supply available of all doses of both Ozempic® ▼ (once-weekly semaglutide) and RYBELSUS® ▼ (semaglutide tablets), should you be seeking a GLP-1 RA to prescribe for adults with type 2 diabetes at this time.*

Stating that Novo Nordisk's priority was maintaining supply of treatment in a message relating to a supply issue with an Eli Lilly product implied that maintaining supply of treatment was not a priority for Eli Lilly. This was clearly disparaging towards Eli Lilly, in breach of Clause 6.6.

Failures to maintain high standards in breach of Clause 5.1

Reference 1 in the promotional emails was entitled 'Department of Health and Social Care. Email confirming Trulicity supply issues; February 2022'. The email was sent to us by the Novo Nordisk Medical Information department upon request and is an email from the DHSC to Novo Nordisk, dated 1 February 2022 (copy provided), stating, 'Just an email to inform you that currently Trulicity is out of stock till April 2022, we will be supplying comms shortly on this shortage but from the clinical advice we have been given, the second option being proposed in the comms to clinicians/prescribers would be to switch patients on an alternative GLP-1 analogue'.

The promotional emails misled the reader regarding the content of the email from the DHSC to Novo Nordisk and the DHSC's stated intentions:

1 The email from the DHSC to Novo Nordisk stated that the stock outage was until April 2022, a date that Novo Nordisk omitted to mention in the promotional emails.

Stating a 'temporary supply issue' was open-ended and ambiguous, and clearly misleading when Novo Nordisk had already been informed of the date of resupply.

2 The email from the DHSC to Novo Nordisk made clear that they would shortly be issuing guidance to HCPs about managing the stock disruption and that switching to an alternative GLP-1 RA was the second (as opposed to preferred) option they would be recommending. The promotional emails misrepresented the DHSC's stated intentions by not making clear that switching to a Novo Nordisk GLP-1 RA was not the preferred option.

Referencing the DHSC and then misrepresenting the content of the referenced email, including the DHSC's stated intentions, was a clear failure to maintain high standards, in breach of Clause 5.1.

The official DHSC notification to health professionals, an MSN, was issued on 10 February 2022 (copy provided). The MSN stated, 'Where patients have insufficient supplies to last until the re-supply date, clinicians should consider temporarily prescribing 1.5mg dulaglutide (see supporting information below). If such a dose reduction is not considered suitable, options include: - Switching to an alternative GLP-1 agonist; the choice of which will likely require specialist input, as well as training on the new pen device; or - the off-label use of multiple 1.5mg injections to make up required dose, though there are no data on efficacy and safety of this approach, and acceptability to patient would need to be ascertained. Specialist advice should be sought if there is uncertainty about the most appropriate management option'.

The guidance to health professionals in the MSN was consistent with the DHSC's email to Novo Nordisk in that switching to an alternative GLP-1 RA was the second option they proposed, the preferred option being temporary reversion to the 1.5 mg dose of dulaglutide. The MSN stated that switching to an alternative GLP-1 RA should be considered only where temporary reversion to 1.5mg Trulicity was not considered suitable, with the choice likely requiring specialist input as well as training on a new pen device. Furthermore, the alternative GLP-1 RAs recommended by the DHSC in the MSN were Bydureon (exenatide), Ozempic (semaglutide) and Victoza (liraglutide).

The MSN was issued on 10 February 2022 and yet Novo Nordisk continued to issue the promotional emails despite them being in conflict, both by omission and commission, with the MSN in several ways:

1 The MSN stated that switching to an alternative GLP-1 RA should be considered only where temporary reversion to 1.5mg dulaglutide was not considered suitable, with the choice likely requiring specialist input as well as training on a new pen device. The promotional emails failed to mention any of this.

2 The promotional emails failed to mention either Bydureon or Victoza, which were appropriate alternatives proposed by the DHSC, but did mention Rybelsus (semaglutide tablets), despite it not being recommended as an alternative by the DHSC.

Sending promotional emails that were clearly in conflict with DHSC guidance, whilst continuing to reference a DHSC email rather than the official DHSC MSN, was highly inappropriate and misleading, demonstrating a failure to maintain high standards, in breach of Clause 5.1.

Bringing discredit upon the pharmaceutical industry

The Novo Nordisk promotional emails were clearly a cynical attempt to take commercial advantage at a time when a competitor was facing the sort of temporary supply issue that all companies, including Novo Nordisk, faced from time-to-time. Doing so in a way that disparaged the company that was facing the supply issue, and that Novo Nordisk knew to be in conflict, both by omission and commission, with guidance from the UK government department responsible for government policy on health, whilst referencing that department, was egregious and a matter of the most serious nature, bringing discredit upon the pharmaceutical industry, in breach of Clause 2.

Lilly stated that given the very serious nature of its concerns that the emails misled health professionals about the guidance from the DHSC on managing the issue, with its implications for patient care, Eli Lilly requested that Novo Nordisk send a letter and email of correction to all recipients of their promotional emails, correcting all misrepresentations. They twice declined to do so. Furthermore, Eli Lilly requested that given the completely unacceptable nature of the promotional emails in this context and the consequent harm, Novo Nordisk should self-report the breaches to the PMCPA. They agreed to do so, but only for some aspects of the matter.

Given this, Eli Lilly had escalated the matter, alleging breaches of Clauses 6.6, 5.1 and 2 of the 2021 Code.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 6.6, 5.1 and 2 of the Code as cited by Eli Lilly.

RESPONSE

Novo Nordisk provided a copy of the email (UK22OZM00010) subject to the complaint together with the certificate approving the material. The qualification of the signatory was provided.

Background

Novo Nordisk submitted that the email template was:

- Certified as a promotional item.
- Available for both proactive and reactive use by Novo Nordisk diabetes sales representatives to send to health professionals (HCPs) via Outlook email.
- Issued out for use on 3 February 2022 and withdrawn from circulation on 16 March 2022. During this time, the email was sent to a total of 873 health professionals.

Novo Nordisk stated that for the purpose of providing a complete response, another email with identical content to UK22OZM00010 was also produced for sales representative use. UK22RYB00026 (copy provided) was created specifically as a representative triggered email (RTE) which could be sent upon request from a health professional via Novo Nordisk's Customer Relationship Management (CRM) system. The email was available for use between 9 February 2022 and 16 March 2022. This email was sent to 13 health professionals. The qualification of the signatory that certified this email was the same as that provided above.

Purpose of the email

Novo Nordisk stated that it had been received multiple reports, via various sources, that Eli Lilly was facing issues with its supply of the higher doses (3.0 mg and 4.5 mg weekly) of Trulicity (dulaglutide), a GLP1-receptor agonist (GLP1-RA). The issue of supply was confirmed by the Department of Health and Social Care (DHSC) to Novo Nordisk via email on 1 February 2022 (copy provided). This DHSC email was included as a reference within email UK22OZM00010 to support the statement made regarding the supply issue.

The reports of supply issues were driving health professionals to enquire with Novo Nordisk's field teams as to the availability of Novo Nordisk GLP1-RAs. While email UK22OSM00010 did refer to the temporary Trulicity supply issue, this detail was only included in the context of acknowledging the enquiries Novo Nordisk was receiving from health professionals following reports of supply issues. The fundamental purpose of the email was as follows:

1 To notify health professionals that Novo Nordisk was not facing supply issues for its most recently launched GLP-1 RAs, Ozempic and Rybelsus.
2 To advise health professionals that Novo Nordisk was able to provide a range of materials to support the health professional if they were considering initiating a patient on Ozempic or Rybelsus.

Alleged disparagement of Eli Lilly

Novo Nordisk was of the view that all companies took product supply extremely seriously. The inclusion of a statement in the email template about Novo Nordisk maintaining supply of treatment in no way inferred that Eli Lilly's commitment to product supply was lacking.

Alleged failure to maintain high standards

To be absolutely clear, the email was not prepared as means to provide health professionals with the specific details of the Trulicity supply issue and hence the date on which it was anticipated that stock would be restored was not included.

Furthermore, the email was not prepared to provide information to health professionals on the DHSC guidance as to how to manage those patients currently on Trulicity 3.0g or 4.5mg. The email made no reference to switching patients and in no way did the content of the email infer that switching patients on 3.0mg or 4.5mg Trulicity to a Novo Nordisk GLP-1 RA was the preferred option to manage patients. As a result, it was not deemed necessary to include details on the options provided within the Medicines Supply Notification (MSN) on managing patients. Therefore, reference to Rybelsus was included and reference to Victoza and Bydureon was not. This was consistent with Novo Nordisk's purpose for creating the email, as described above.

Allegation that Novo Nordisk had brought discredit upon the pharmaceutical industry

Novo Nordisk stated that given the intended purpose of the email, Novo Nordisk remained of the clear view it had not disparaged Eli Lilly and there had been no misrepresentation of DHSC guidance. Consequently, Novo Nordisk disagreed that the email brought discredit upon and reduced confidence in the industry. As a result, Novo Nordisk denied a breach of Clauses 2, 5.1 and 6.6 of the Code.

PANEL RULING

The Panel considered Eli Lilly's allegation that the statement 'Novo Nordisk's priority is maintaining supply of treatment to support adults living with type 2 diabetes' in a message relating to a supply issue with an Eli Lilly product implied that maintaining supply of treatment was not a priority for Eli Lilly and was thus disparaging towards Eli Lilly. The Panel noted Novo Nordisk's submission that all companies took product supply extremely seriously and the inclusion of a statement in the email template about Novo Nordisk maintaining supply of treatment in no way inferred that Eli Lilly's commitment to product supply was lacking.

Clause 6.6 stated that the medicines, products and activities of other pharmaceutical companies must not be disparaged. Whilst the Panel did not consider it unreasonable for Novo Nordisk to refer to its ability to maintain supply of its products the Panel considered that including the statement 'Novo Nordisk's priority is maintaining supply of treatment to support adults living with type 2 diabetes' followed by 'We can reassure you as an HCP, that we have supply available of all doses of both Ozempic® ▼ (once-weekly semaglutide) and RYBELSUS® ▼ (semaglutide tablets), should you be seeking a GLP-1 RA to prescribe for adults with type 2 diabetes at this time' directly below reference to Eli Lilly having supply issues was such that it implied that maintaining supply of treatment was not a priority for Eli Lilly and thus was disparaging towards Eli Lilly as alleged and **a breach of Clause 6.6** was ruled.

The Panel noted Eli Lilly's allegations that the promotional emails in question misled the reader regarding the content of the email from the DHSC to Novo Nordisk dated 1 February 2022 and the DHSC's stated intentions which was a failure to maintain high standards. In this regard Eli Lilly stated that the email from the DHSC to Novo Nordisk stated that the stock outage was until April 2022, a date that Novo Nordisk omitted to mention in the emails; a 'temporary supply issue' was open-ended and ambiguous, and clearly misleading when Novo Nordisk had already been informed of the date of resupply, and the email from the DHSC to Novo Nordisk made clear that they would shortly be issuing guidance to health professionals about managing the stock disruption and the promotional emails misrepresented the DHSC's stated intentions by not making clear that switching to a Novo Nordisk GLP-1 RA was not the preferred option.

The Panel considered that whilst it would have been helpful for Novo Nordisk to refer to the fact that the supply issue was until April 2022, the emails did refer to the supply issue as being temporary and referred to notifications issued by Lilly which would have likely included such detail. The Panel further noted the statement, which was emboldened - 'If you are considering initiating a patient on GLP-1 RA therapy'; there was no mention in the emails that switching a patient to a Novo Nordisk GLP-1 RA therapy was the preferred option. The Panel therefore did not consider that the emails misled the reader regarding the content of the referenced email from the DHSC to Novo Nordisk or misrepresented the DHSC's intentions as alleged. The Panel noted its comments above and did not consider that there was evidence to show that Novo Nordisk had failed to maintain high standards in this regard and **no breach of Clause 5.1** was ruled.

The Panel noted Lilly's further allegation that the MSN was issued on 10 February 2022 yet Novo Nordisk continued to issue the promotional emails despite them being in conflict, both by omission and commission, with the MSN in several ways. In this regard, Lilly noted that the MSN stated that switching to an alternative GLP-1 RA should be considered only where temporary reversion to 1.5mg dulaglutide was not considered suitable, with the choice likely requiring specialist input as well as training on a new pen device which the emails failed to mention and the emails failed to mention either Bydureon or Victoza which were appropriate

alternatives proposed by the DHSC, but did mention Rybelsus (semaglutide tablets) despite it not being recommended as an alternative by the DHSC.

The Panel noted that the MSN stated beneath the heading 'Other GLP-1 agonists' that 'There are two other once weekly GLP-1 agonists licensed for the treatment of type 2 diabetes mellitus, Bydureon (exenatide) and Ozempic® (semaglutide), as well as a once daily agent, Victoza (liraglutide). If a switch to these preparations is being considered, advice should be sought from specialists on which agent to switch to, and patients will require training on using the new pen device'. The Panel noted Novo Nordisk's submission that the email was not prepared to provide information to health professionals on the DHSC guidance as to how to manage those patients currently on Trulicity 3.0g or 4.5mg; the email made no reference to switching patients and in no way did the content of the email infer that switching patients on 3.0mg or 4.5mg Trulicity to a Novo Nordisk GLP-1 RA was the preferred option to manage patients. As a result, Novo Nordisk did not deem it necessary to include details on the options provided within the Medicines Supply Notification (MSN) on managing patients and reference to Rybelsus was included and reference to Victoza and Bydureon was not which was consistent with Novo Nordisk's purpose for creating the email which was according to Novo Nordisk to notify health professionals that Novo Nordisk was not facing supply issues for its most recently launched GLP-1 RAs, Ozempic and Rybelsus and to advise health professionals that Novo Nordisk was able to provide a range of materials to support the health professional if they were considering initiating a patient on Ozempic or Rybelsus.

The Panel, noting its comments above, did not consider that the promotional emails were in conflict with DHSC guidance with regards to when switching to an alternative GLP-1 RA should be considered, nor that referring to Rybelsus and not Bydureon and Victoza, and nor that continuing to reference a DHSC email rather than the official DHSC MSN was inappropriate and misleading as alleged and based on the complainant's allegations **no breach of Clause 5.1** was ruled in this regard.

The Panel did not consider that the particular circumstances of the case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use and **no breach of Clause 2** was ruled.

Complaint received **31 May 2022**

Case completed **5 April 2023**