

**HEALTH PROFESSIONAL v NOVO NORDISK**

Allegations regarding funding of a health professional's salary

**CASE SUMMARY**

This case was in relation to a named obesity practitioner's salary, which the complainant alleged had been funded by Novo Nordisk as an inducement to prescribe its medicines. The complainant further alleged that around the time Novo Nordisk paid for the healthcare organisation to have this additional member of staff, the healthcare organisation relaxed its local criteria for use of liraglutide to increase use of the medicine.

In relation to the allegations about the funding of the named obesity practitioner's salary, the Panel ruled no breach of the following clauses of the 2019 Code:

<b>No Breach of Clause 2 (Unsuccessfully appealed)</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 9.1 (Unsuccessfully appealed)</b>	<b>Requirement that high standards must be maintained at all times</b>
<b>No Breach of Clause 18.1 (Unsuccessfully appealed)</b>	<b>Requirement that no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine</b>
<b>No Breach of Clause 19.1 (Unsuccessfully appealed)</b>	<b>Requirement that medical and educational goods and services can be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit.</b>
<b>No Breach of Clause 19.2 (Unsuccessfully appealed)</b>	<b>Requirement that the provision of medical and educational goods and services in the form of donations, grants and benefits in kind to healthcare organisations are only allowed if they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.</b>
<b>No Breach of Clause 21 (Unsuccessfully appealed)</b>	<b>Requirement that contracts between companies and organisations under which such organisations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding) do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.</b>

Regarding the allegations about the influence of the salary funding on the healthcare organisation's liraglutide clinical guideline, the Panel ruled no breach of the following clauses of the 2019 Code:

<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 9.1</b>	<b>Requirement that high standards must be maintained at all times</b>
<b>No Breach of Clause 18.1</b>	<b>Requirement that no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine</b>
<b>No Breach of Clause 19.1</b>	<b>Requirement that medical and educational goods and services can be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit.</b>
<b>No Breach of Clause 19.2</b>	<b>Requirement that the provision of medical and educational goods and services in the form of donations, grants and benefits in kind to healthcare organisations are only allowed if they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.</b>
<b>No Breach of Clause 21</b>	<b>Requirement that contracts between companies and organisations under which such organisations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding) do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.</b>

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

## **FULL CASE REPORT**

A complaint was received from a contactable health professional about the conduct of Novo Nordisk Ltd.

## **COMPLAINT**

The complainant alleged that for the past two years, Novo Nordisk had funded the salary of a named obesity practitioner at a named hospital. The complainant alleged that the primary function of this staff member was to commence patients on Novo Nordisk medicines (liraglutide and semaglutide) and to support the use of those medicines. The gift of this salary to the hospital was allegedly promotion of Novo Nordisk medicines and an inducement to prescribe those medicines, contrary to Clause 19.1 of the 2021 Code.

The complainant further alleged that around the time Novo Nordisk paid for the hospital to have an additional staff member, the hospital relaxed their local criteria for use of a Novo Nordisk medicine to increase the scope of its local use.

As stated above, the complainant alleged that Novo Nordisk had paid the salary of an NHS staff member, whose primary function was allegedly to commence patients on Novo Nordisk medicines (liraglutide and semaglutide) as an inducement to prescribe those medicines, contrary to the Code. Furthermore, in 2020, obesity services at the hospital in question relaxed their criteria for giving patients a Novo Nordisk drug (liraglutide). Instead of following the National Institute for Health and Clinical Excellence (NICE) guidance, the hospital's local guidance was more permissive and allowed liraglutide treatment in circumstances outside of NICE recommendations.

The 2020 Liraglutide NICE technology appraisal guidance stated that liraglutide may be prescribed by 'a specialist multidisciplinary tier 3 weight management service'. The complainant stated that the named hospital was not a tier 3 weight management service and so the NICE guidance did not permit it to use liraglutide. The complainant stated that under 2020 NICE guidance there was no need and no obligation for the hospital to use liraglutide at all. However, in 2020, the hospital initiated an active liraglutide service. The complainant alleged that there was inducement to prescribe liraglutide contrary to the Code, and that at the time of the inducement, favourable local guidelines were introduced which did in fact increase use of liraglutide.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 5.1, 19.1, 23.1, 23.2 and 24.3 of the 2021 Code.

## **RESPONSE**

Novo Nordisk submitted that the funding in question was approved in 2018 and paid in 2019 and so it had made reference to the relevant clauses in the 2019 Code of Practice which would have covered the activity at that time.

Novo Nordisk submitted that the request pre-dated any requirement to certify such funding and, other than a record of payment, it did not have any centralised archive of documentation relating to this. Novo Nordisk had therefore had to focus its investigation on speaking to Novo Nordisk staff and individual email records.

## **Summary of the funding**

Novo Nordisk submitted that the named hospital requested financial support from Novo Nordisk in 2018. It was establishing a specific clinic to treat patients with pre-diabetes and obesity. The clinic would form part of a larger multi-disciplinary team (MDT) in obesity with a focus on pre-

diabetes. Following discussions with Novo Nordisk, the team at the hospital requested funding to employ a dietician and fitness trainer to be part of the MDT within the clinic, as this was an identified gap in their service at that time.

Novo Nordisk stated that it assessed and approved the funding request for a total of £35,000 for both roles, for a period of one year only. The funding was approved using a Support Approval Submission form which was a global internal assessment document, specifically used for funding requests in the obesity therapy area. This request was approved on 1 December 2018. It was a one-off payment and no additional funding was given in subsequent years.

### **Chronology**

Novo Nordisk submitted that it received two written requests from the hospital for funding on 28 November 2018 and a revised request for funding on 2 December 2018. The original written request made reference to use of Novo Nordisk's medicine, liraglutide 3.0mg. The request was not approved on the basis of using a Novo Nordisk medicine; this was against the Novo Nordisk corporate requirements and, of course, was contrary to the requirements of the Code in place currently and at the time, that funding such as grants and donations could not be linked to the use of a specific medicine(s). Further, NICE final recommendation for use of liraglutide 3.0mg in obesity was published on 9 December 2020 and, up until this point, it was not reimbursed on the NHS. The approval of the request occurred 2 years prior to liraglutide 3.0mg being available on the NHS, and the role in relation to the funding was for 12 months only, approved in 2018.

The revised written request explained in more detail how the clinic would fit within the multi-disciplinary team for obesity offering the full treatment options to patients with pre-diabetes and obesity. In this request, reference was made to funding to support a specialist nurse to provide diet and exercise advice.

An agreement was signed on 21 December 2018. The agreement stated that the purpose of the funding was to ensure correct functioning of the multi-disciplinary team. The funding was paid directly to the hospital in early 2019.

Novo Nordisk submitted that there was no obligation on the hospital to provide any benefits in return for the funding, therefore Novo Nordisk denied a breach of Clauses 19.1 and 19.2 of the 2019 Code in this regard (Clause 23.1 of the 2021 Code). In addition, it was not provided as an inducement to recommend Novo Nordisk products and therefore not a breach of Clause 19.2 of the 2019 Code of Practice (Clause 23.2 of the 2021 Code).

Novo Nordisk submitted that the funding was not provided to a named individual and there was no inducement to prescribe. Novo Nordisk therefore denied a breach of Clause 18.1 of the 2019 Code of Practice (Clause 19.1 of the 2021 Code).

Novo Nordisk submitted that there was no provision of contracted services between Novo Nordisk and the named hospital, or between Novo Nordisk and the person who was recruited by the hospital therefore Clause 21 of the 2019 Code (Clause 24.3 of the 2021 Code) was not relevant and Novo Nordisk denied a breach in that regard.

### **Named hospital local guidance for use of liraglutide**

Novo Nordisk submitted that the provision of the funding by Novo Nordisk had no influence on the guidance produced by the named hospital with regard to the use of liraglutide for the treatment of obesity. It was the decision of each hospital trust to decide which patient populations might be suitable for certain medications approved by NICE. Each individual hospital/trust had its own governance process and would make its own internal decision on how to implement the NICE recommendations depending on circumstances within the trust.

Novo Nordisk understood that the decision to implement NICE recommendations was made by the executive management team of the hospital in 2020 due to high, unmet need and to avoid inequalities in the provision of care as other trusts in and around the same area had already implemented the NICE recommendation. The funding was paid in January 2019 and was completely unrelated to the decision made by the hospital to implement the recommendations and pathway.

There were two criteria approved internally by the hospital for the use of liraglutide; criteria 1 was fully aligned to NICE recommendations, criteria 2 was approved to address a specific unmet need for a specific subset of morbidly obese patients who were waiting to undergo bariatric surgery post-covid pandemic and impacted by the backlog of patients awaiting surgery (as provided by the complainant – the named hospital 2020 guidelines liraglutide). Both these decisions were an internal matter of the trust, and Novo Nordisk understood that they followed a robust internal approval process to implement this pathway due to the huge unmet need for people living with obesity.

To conclude, Novo Nordisk submitted that it had maintained high standards and had not brought the industry into disrepute and therefore denied a breach of Clauses 9.1 and 2 of the 2019 Code (Clauses 5.1 and 2 of the 2021 Code).

In response to a question from the case preparation manager as to whether there had been other payments made to the hospital since 2018, Novo Nordisk submitted that it had provided two separate grant payments to the hospital since 2018, however neither grant related to the funding of an obesity practitioner. Details of the two payments were provided:

Year	Amount	Purpose
2021	£75000	Funding of a Senior Clinical Scientist as a Research Programme Lead to support Type 2 diabetes and obesity research
2021	£71500	Funding a Research Assistant and Statistician/Data Analyst who will provide support for research coordination and data analysis for a Global registry.

Novo Nordisk submitted that given the complainant in this case referred specifically to ‘funded the salary of an obesity practitioner’ it did not consider that the above information was relevant to this matter.

## PANEL RULING

The Panel noted the complainant's allegation that for 'the past two years' Novo Nordisk had funded the salary of a named obesity practitioner at a named hospital whose primary function was to commence patients on Novo Nordisk medicines and support the use of those medicines. The complainant alleged that the gift of this salary was promotion of Novo Nordisk medicines and an inducement to prescribe.

The Panel considered that the complaint was clear that the named funded obesity practitioner had been in place 'for the past two years' and in this regard noted that the complaint was submitted to the Authority in March 2023.

The Panel noted Novo Nordisk's submission that the hospital was establishing a clinic to treat patients with prediabetes and obesity which would form part of a larger multi-disciplinary team in obesity with a focus on prediabetes. According to Novo Nordisk, following discussions with the team at the hospital, it requested funding from Novo Nordisk to employ a dietician and fitness trainer to be part of the multi-disciplinary team, as this was an identified gap in their service at that time. Novo Nordisk assessed and approved the funding request for a total of £35,000 for both roles, for a period of one year only. The funding was approved using a Support Approval Submission form which was specifically used in Novo Nordisk for funding requests in the obesity therapy area. Novo Nordisk stated that the request was approved on 1 December 2018 and paid in January 2019; it was a one-off payment, and no additional funding was given in subsequent years.

The Panel noted that Novo Nordisk received two written requests from the hospital for funding; the first dated 28 November 2018 and a revised request for funding dated 2 December 2018. The original written request dated 28 November referred to use of Novo Nordisk's medicine, liraglutide 3mg, referring to discussions with Novo Nordisk and the establishment of a specific clinic to treat patients with prediabetes and obesity, then stating 'We want to show the benefit of liraglutide 3mg in this cohort within a real world setting.'

The revised written request dated 2 December (a day after the funding had been approved by Novo Nordisk) explained in more detail how the clinic would fit within the larger multi-disciplinary obesity team offering the full treatment options to patients with prediabetes and obesity. This request, which did not refer to liraglutide, made it clear that the funding would be used to support a specialist nurse to provide diet and exercise advice. The Panel was concerned about the differences between the two written requests from the hospital and the differences between these written requests and what was approved by Novo Nordisk in the 'Support Approval Submission' document which referred to two roles: a dietician (£20,000) and a physical trainer (£15,000). The 2 December email from the hospital referred to the funding being used for one role, a specialist nurse. The Panel was further concerned that the funding was approved on 1 December, prior to receipt of the revised request from the hospital on 2 December. The Panel had no information about the discussions that occurred with the hospital before each funding request was submitted.

Novo Nordisk had submitted that the request was not approved on the basis of using a Novo Nordisk medicine stating that this was against the Novo Nordisk corporate requirements and the requirements of the Code. Further, the NICE final recommendation for liraglutide for managing overweight and obesity (TA664) was published 9 December 2020; Novo Nordisk stated that up until this point it was not reimbursed on the NHS. The Panel noted that the approval of the request for support to the hospital occurred approximately 2 years prior to liraglutide for managing

overweight and obesity becoming available on the NHS, and further that it was provided as a one-off payment in January 2019 to cover a period of 12 months only.

The Panel noted that the written donation agreement, signed 21 December 2018, referred to financial support of £35,000; the purpose stated was to ensure correct functioning of the multi-disciplinary team so that the recipient can provide full support for people with obesity. It appeared to the Panel that there was no contractual obligation on the hospital to provide any benefits in return for the funding. The Panel noted that the agreement did not provide the breakdown of fees as referred to in the 'Support Approval Submission'. The written donation agreement stated 'recruitment process will kick-off in January 2019' but did not describe the position(s) being recruited for or the number. Clause 3(j) of the written agreement required the hospital to provide a written report to Novo Nordisk describing how the donation had been allocated in relation to the purpose. The Panel did not know if Novo Nordisk received this report; no such report had been provided to the Panel.

The Panel was not an investigatory body as such. It asked the respondent company for a complete response. The complainant had the burden of proving their complaint on the balance of probabilities.

It was not clear to the Panel what exactly the £35,000 paid to the hospital in January 2019 was used for, including whether it was for one individual or two and the job title(s). Further, the Panel had no evidence before it as to the date such individual(s) commenced their role at the hospital.

The Panel noted that the funding was approved, and the written agreement signed by both parties, in December 2018 and queried whether the complaint should be dealt with under the 2016 Code which was in operation at that time. The Panel further noted that the payment was made in 2019 and the agreement stated that recruitment would commence that year. Novo Nordisk had responded in relation to the 2019 Code. There were no material differences between the 2016 and 2019 Codes in relation to the clauses at issue so the Panel made its rulings under the 2019 Code.

The Panel had concerns about the overall governance, for instance the Support Approval Submission Form was not complete and implied that the total funding was for two discrete roles which appeared to be inconsistent with other documentation. There was no evidence before the Panel about how the hospital used the funds and this was particularly concerning given the limited information in the written donation agreement and the discrepancies between the two written requests from the hospital and between these and the Support Approval Submission Form in relation to the purpose of the funding.

The Panel noted that the complaint was clear that the obesity practitioner had been funded 'for the past two years' and further noted that the complaint was received in March 2023. The one-off funding was provided in January 2019, following execution of the written agreement in December 2018, and approximately 4 years and 2 months prior to the submission of the complaint to the Authority. Whilst the Panel did not necessarily expect the complainant to provide exact dates it noted that the complaint was clear about the two year period which would mean that, according to the complainant, the funded individual who was the subject of the complaint was in place from approximately March 2021, more than 2 years after the funds were actually provided. The Panel had no information before it to demonstrate whether the named medical obesity specialist practitioner, referred to by the complainant, was funded by the January 2019 payment to the hospital.

The Panel noted that, in response to a request for further information from the case preparation manager, Novo Nordisk provided details of funding provided in 2021 which related to: the funding of a senior clinical scientist as a research programme lead to support Type 2 diabetes and obesity research; and the funding of a research assistant and statistician/data analyst to support a global registry. In the Panel's view, whilst this funding was provided within the time period stated by the complainant, neither of these roles could reasonably be described as an obesity practitioner and therefore in the Panel's view neither was the subject of the complaint. The Panel noted that the complainant bore the burden of proof and whilst the Panel was deeply concerned about the governance associated with the January 2019 payment to the hospital, it had no evidence before it that this payment was the subject of complaint. On the narrow ground that the January 2019 payment did not appear to fund the salary of the named obesity practitioner referred to by the complainant, the Panel ruled **no breach of Clauses 2, 9.1, 18.1, 19.1, 19.2, and 21 of the 2019 Code** in relation to that payment.

The Panel noted the complainant's further allegation that around the time Novo Nordisk paid for the hospital to have an additional staff member, it had relaxed their local criteria for use of liraglutide to increase local use of the medicine. The complainant provided the hospital liraglutide clinical guideline dated July 2020. The Panel noted that the introduction section of this guideline referred to a recently completed prospective randomised real world evidence study conducted by the hospital, evaluating the efficacy of Saxenda as bridging therapy in patients with complex obesity followed in a Tier 3/4 bariatric service. The Panel noted that the date of the guideline appeared to pre-date the NICE TA664 guidance for liraglutide for managing overweight and obesity, published 9 December 2020. It also appeared to pre-date the two 2021 Novo Nordisk funded positions described above, and the position of the named obesity practitioner referred to by the complainant who had allegedly been funded by Novo Nordisk for the two years prior to March 2023. The Panel further noted that there was almost 18 months between the January 2019 payment to the hospital described above and the date of the liraglutide clinical guideline in question, dated July 2020. The Panel, noting that the complainant bore the burden of proof, had no evidence before it that Novo Nordisk funding of hospital staff as described above had any improper influence on the development of the hospital liraglutide clinical guideline in question. On this narrow ground the Panel ruled **no breach of Clauses 2, 9.1, 18.1, 19.1, 19.2 and 21 of the 2019 Code**.

## **APPEAL BY COMPLAINANT**

1. The specific aspect the complainant was appealing related to the allegation that Novo Nordisk funded the salary of a named obesity practitioner, whose primary function was to commence Novo Nordisk obesity medications. This gifted salary was alleged to be contrary to the 2019 Code of Practice.
2. The Panel's ruling stated that 'On the narrow ground that the January 2019 payment did not appear to fund the salary of the named obesity practitioner referred to by the complainant, the Panel ruled no breach of [the Code] in relation to that payment'.
3. The basis of the appeal was that, as a point of fact, the £35,000 payment by Novo Nordisk in January 2019 was used to fund the salary of the named obesity practitioner who commenced their post in Spring/Summer 2021. This fact was said to be common knowledge and widely accepted within the hospital. As evidence of this fact the complainant provided email correspondence from two colleagues and minutes of a meeting, which the complainant



considered confirmed that the 2019 payment from Novo Nordisk was used to pay the salary referred to above.

Therefore, the complainant stated that the revised allegation was as follows:

4. That the named hospital made a request for funding from Novo Nordisk in November/December 2018, and in response to this a £35,000 donation was made to the hospital. The money was paid in January 2019.

5. This one-off lump sum of money (£35,000) was kept in reserve by the hospital, and was subsequently used to fund the initial salary of the named obesity practitioner when they were employed.

6. The obesity practitioner's primary role was to initiate patients onto a Novo Nordisk medication (liraglutide), they also supported the dose titration process and gave patients advice and support on weight loss. To support this fact the complainant provided the standard operating procedure for the obesity practitioner's clinic.

7. It was alleged that Novo Nordisk knew, or ought to have known, that the £35,000 that it paid the hospital was likely to be used for liraglutide initiation. The evidence for this was firstly that the initial request for funding, on 28 November 2018, made reference to using the funds to establish a clinic to treat patients with liraglutide 'within a real world setting'. This was a finding of the Panel ruling of 25 October 2023.

8. Secondly, there was evidence that Novo Nordisk was in close email communication with the hospital obesity clinicians during 2020/2021 about the development of obesity services (copy provided, which was an example of email contact between a Novo Nordisk employee and the obesity services at the hospital). It was implausible that Novo Nordisk had no knowledge of the plan to establish a pharmacotherapy service using the previously donated funds.

9. It was alleged therefore that the payment breached Clauses 2, 9.1, 18.1, 19.1, 19.2 and 21 of the 2019 Code.

#### **APPEAL RESPONSE FROM NOVO NORDISK**

Novo Nordisk submitted that the initial request for the funding at issue in this case was received by Novo Nordisk UK in July 2018. Specifically, the request was to support a new clinical service for patients with prediabetes, BMI >35 in a tertiary university hospital setting.

Initially this was treated as a potential grant request and in scope for Global Novo Nordisk funding under a non-promotional service development initiative. The initiative objective was to advance quality of care globally as per each countries' local requirements.

The original completed approval form, and as noted above, detailed that this would be a grant and therefore there would be regular checks over the grant period (in this case 1 year) to ensure that the money was used as agreed. At this point the request was specifically for funding to support two roles; a dietician and a physical trainer.

Novo Nordisk submitted that the grant was approved in the UK and sent to the Global team in September 2018. However, for reasons that Novo Nordisk were not fully able to establish, at

some point in approximately November 2018, the funding was reclassified internally as a donation. Whilst this seemed insignificant from a Code perspective (given that in the 2016 Code the terms grant and donation were used interchangeably) this approach led to no follow-up with the donation recipient as to whether the funds were used as agreed. In addition, it seemed that there was a requirement to again internally approve provision of the funding.

The support approvals submission form was revised for reapproval, still referencing that the funds were for a dietician and a physical trainer but now referring to a donation rather than a grant, with 'N/A' placed in the sections relating to follow-up.

Novo Nordisk submitted that on 28 November 2018, the hospital again requested the funds, this time in the form of a donation and unfortunately the email request from the hospital used language that was inappropriate. The [named health professional], who sent the email, was asked by Novo Nordisk to revise this request in order to provide more detail on the need to set up an Obesity MDT clinic to enable a full review of the application by the global Novo Nordisk funding team. Suggestions were made as to what the revised request might say, based on previous conversations.

Novo Nordisk submitted that this email request of 28 November 2018 was provided to those in the UK that approved the donation; however, given that they had seen the application previously in the form of a grant, they did not rely on this email as the reason for the application. In addition, it appeared the approvers were informed that a revised request was pending, and the donation was approved in the UK on 1 December 2018. A revised request was received from the hospital on 2 December, and this seemed to be the first time that there was reference to using the funds to hire a 'specialist nurse who can also help deliver diet and exercise', which explained the discrepancy between the approval form and the final request. The PMCPA Panel raised the concern that the funding was approved on 1 December, prior to receipt of the revised request from the hospital on 2 December. Novo Nordisk acknowledged that due process seemed not to have been followed in this case and it seemed, in an attempt to meet internal year-end account closing timeline, the approval happened a day before the revised request was submitted.

The request in the form of a donation was approved in December and the contract fully signed by both parties on 21 December 2018. It also appeared that payment was made on 28 December 2018.

Novo Nordisk considered that the matter appeared to be a legitimate request for funding from the hospital that was approved internally and fulfilled from budget appropriately allocated for non-promotional purposes. The classification internally of the funds as a donation meant that, unfortunately, there was no follow-up in terms of the use of the funds and Novo Nordisk were unaware that the payment was not utilised as expected in 2019. After receiving the request for appeal, and in order to address the gaps raised by the Panel, Novo Nordisk had requested further information from the hospital and the current responsible teams to bring further clarity to the utilisation of this funding at the hospital and the relevant context on the settings this fund had been used.

Novo Nordisk submitted that, from historical documentations reviewed, whilst there had been some process related errors and inconsistencies in terms of categorising and approving this funding, there was no evidence of any inducement in the approval forms or written agreement. There was also no indication that the recipient organisation considered there was any expectation from Novo Nordisk, or any obligation on the part of the hospital, to use liraglutide in

return for the donation. Indeed, and as noted in Novo Nordisk's initial response to this complaint, the medicine was not available on the NHS at the time the donation was approved and paid, nor for some years afterwards; it did not become available until March 2021. The complainant had raised concerns on inappropriate use of Novo Nordisk medicine at the hospital; as Novo Nordisk was not in a position to comment on the specific hospital governance, Novo Nordisk had requested further clarity from the relevant consultant teams to describe how services were being run at the hospital. Of note the [named health professional] who originally requested this funding on behalf of the hospital was no longer there.

In the complainant's appeal there was reference to 'close email communication with [hospital's] obesity clinicians during 2020/2021 about the development of obesity services'. The complainant appeared to have mistaken the communication as evidence that Novo Nordisk had knowledge '...of the plan to establish a pharmacotherapy service using the previously donated funds'. This email related to a multicentred non-commercial product donation to multiple centres across the UK as a result of COVID-19 pandemic to address the cancellation of bariatric surgeries for the vulnerable patient group whilst elective surgeries were on-hold; this was limited to Tier 4 services and an example of the Product donation contract was provided.

Novo Nordisk did not consider that there had been any inducement to prescribe and therefore denied any breach of Clauses 18.1, 19.1, 19.2, 9.1 or 2 of the 2019 ABPI Code. Given that there were no services provided to Novo Nordisk by the hospital in this context, Novo Nordisk did not consider that Clause 21 was relevant, and denied any breach in that regard.

#### **FINAL COMMENTS FROM COMPLAINANT**

There were no final comments from the complainant.

#### **APPEAL BOARD RULING**

The Appeal Board observed that they were determining the narrow allegation that Novo Nordisk had funded the salary of a named obesity practitioner, whose primary function was to commence patients on Novo Nordisk obesity medicines, and that this gifted salary was an inducement to prescribe.

Both the complainant and Novo Nordisk had provided the Appeal Board with additional details that had not been before the Panel.

Novo Nordisk's response to the Appeal now stated that the initial request from the hospital for funding was received in July 2018 (not November 2018) for support of a new clinical service for patients with prediabetes, BMI >35 in a tertiary university hospital setting. According to the initial Novo Nordisk approval form, the funds would be provided in the form of a grant of £35,000 for a dietician and physical trainer, and there would be follow up with the hospital as to whether the funds were used as agreed.

The Appeal Board took account of Novo Nordisk's submission that, for reasons unknown to the company, the funding was reclassified in November 2018 as a donation, at the around the same time the hospital had sent a further email, which stated 'We want to show the benefit of liraglutide 3mg in this cohort within a real-world setting'. Novo Nordisk asked the hospital to revise the wording of the request, which it did, on 2 December; the revised request made no reference to liraglutide but now stated that the funding was for a specialist nurse. Novo Nordisk had already

approved the funding the day prior to the revised request; Novo Nordisk acknowledged that due process was not followed but that the approvers knew that a revised request was expected, and they wanted to meet internal year-end account closing timelines. According to Novo Nordisk, the reclassification from a grant to a donation meant there was no follow-up with the recipient as to how the funds were used as this was not a requirement of the company's donation policy at that time.

The Appeal Board noted that the written agreement stated 'recruitment process will kick-off in January 2019' but did not describe the position being recruited for or the number. It further stated, 'In the event the donation is provided and the Purpose does not proceed, for whatever reason within 3 months of the provision of the Donation, Novo Nordisk may demand any financial Donation is returned to Novo Nordisk in full and any further Donation ceases.' The representatives from Novo Nordisk at the appeal said that the onus was on the recipient to inform Novo Nordisk if the funds were not used, and it was unaware that the funds were not utilised in 2019 as expected until receipt of the complaint in 2023.

The Appeal Board observed the complainant's submission that the named obesity practitioner commenced their role in Spring/Summer 2021. An email provided by Novo Nordisk from the hospital stated that the role was part funded by Novo Nordisk and part funded by a named hospital department for about 6 months and that the role is now exclusively funded by the named hospital department. The email from the hospital further stated that the role is partly supporting cardiology research and partly seeing patients who meet the criteria for Saxenda initiation. The Appeal Board considered that while the role in question was not a prescriber role it was an integral part of the clinical team that commenced patients on Saxenda at the hospital.

The Appeal Board was concerned about the language used in emails related to the funding; in July 2018 a Novo Nordisk employee referred to the hospital's request as '...fantastic to see if we could "pilot" our plans for NICE in a real life setting' and the November 2018 email from the hospital referred to wanting to show '...the benefit of liraglutide 3mg in this cohort within a real world setting'. Novo Nordisk said that it did not know what its employee was referring to in July 2018; the individual had now left the organisation. Novo Nordisk further said that some healthcare organisations refer to the company's medicine in their funding requests as they incorrectly believe that it will increase the chance of the funding being provided. However, Novo Nordisk asked the hospital to revise the request in order to provide more detail on the need to set up an Obesity multidisciplinary team clinic.

Novo Nordisk submitted that at the time the funds were paid (28 December 2018), and for some years after, Saxenda (liraglutide 3mg) was not available on the NHS; it did not become available until March 2021.

The Appeal Board noted that the complainant bore the burden of proof. While the Appeal Board was deeply concerned about Novo Nordisk's governance of the funding, it considered, in respect of the narrow allegation, and bearing in mind the chronology of events spanning a number of years, that there was insufficient evidence to support a finding on the balance of probabilities of a direct link that the £35,000 funding to the hospital provided in December 2018 constituted an inducement to prescribe Novo Nordisk obesity medicines. The Appeal Board upheld the Panel's ruling of **no breach of Clause 19.2 of the 2019 Code**.

As the funding was provided to an organisation and not an individual, nor provided to be used for the personal benefit of any individual, the Appeal Board upheld the Panel's ruling of **no breach of Clauses 18.1 and 19.1 of the 2019 Code**.

As the funding did not relate to the hospital providing a service on behalf of Novo Nordisk, the Appeal Board upheld the Panel's ruling of **no breach of Clause 21 of the 2019 Code**.

Consequently, in respect of the narrow allegation, the Appeal Board upheld the Panel's ruling of **no breach of Clauses 9.1 and 2 of the 2019 Code**. The appeal was not successful.

**Complaint received**            **23 March 2023**

**Case completed**                **25 January 2024**