

CASE AUTH/3821/9/23

HEALTH PROFESSIONAL v NOVO NORDISK

Allegations regarding promotion of Saxenda and sponsorship

CASE SUMMARY

This case was in relation to allegations concerning Novo Nordisk actively promoting Saxenda despite supply issues, its provision of free stock to pharmacy chains, sponsorship arrangements, use of sponsorship funding to promote medicines to the public, failure to disclose transfers of value and promotion to the public through its company US websites.

The outcome under the 2019 Code was:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 9.1	Failing to maintain high standards

The outcome under the 2021 Code was:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 5.1 (x2)	Failing to maintain high standards
Breach of Clause 28.1	Failing to document and publicly disclose annually certain transfers of value
No Breach of Clause 3.4	Requirement to comply with all applicable codes, laws and regulations to which the company was subject
No Breach of Clause 5.1 (x 4)	Requirement to maintain high standards
No Breach of Clause 26.1 (x2)	Requirement to not advertise prescription only medicines to the public
No Breach of Clause 26.2	Requirement that information about prescription only medicines which is made available to the public must not encourage the public to ask their health professional to prescribe a specific prescription only medicine
No Breach of Clause 28.1 (x2)	Requirement to document and publicly disclose annually certain transfers of value

**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 an anonymous and non-contactable complainant who described themselves as a health professional about Novo Nordisk Ltd.

COMPLAINT

The complainant submitted that they contacted the PMCPA following shortages of GLP-1 RAs, specifically Saxenda. As a health professional, the complainant stated their priority was to ensure continuity of treatment as part of the care they provided. A standard expectation of the complainant was that the manufacturer had ensured sufficient supply of that medication, especially when it had actively promoted it and continued to do so.

The complainant stated that there was currently no stock of Saxenda whatsoever in the UK, however, there was in other countries. Recent guidance stated that the supplies were not expected to stabilise to meet full market demand until at least mid-2024. The complainant stated surely manufacturing could not have come to a complete halt for so long.

The complainant alleged that Saxenda had not only been actively promoted in both the NHS and the private market by the manufacturers directly, Novo Nordisk had paid significant amounts of sponsorship money to large national pharmacy chains which had online prescribing activities. These included four large national pharmacy chains: Pharmacy Chain A, B, C and D. The purpose was to aid them in setting up their private weight management service. Whilst pharmaceutical sponsorship was commonplace, such sponsorship must be non-promotional. The manufacturer should not have a promotional or commercial incentive when sponsoring third party organisations, especially when they should have been fully aware that they were not able to continue to supply the medication.

The complainant alleged that in addition to the large sums of payments, Novo Nordisk had been supplying these organisations with commercially available products free of cost, which also enabled these businesses to provide Saxenda (and possibly Wegovy very soon) at artificially low prices, and thereby growing the market at an unnaturally fast pace and thus increasing sales of Saxenda and the number of patients accessing the medication. This must have been a factor contributing to the shortage which the manufacturer should be held accountable for.

The funding provided by Novo Nordisk was also used to actively and aggressively promote their services and the prescription medicines (through various media and Google-paid advertisements) directly to members of the public, which was illegal. The complainant believed none of these fundings had been declared. Furthermore, what could only be described as blatant promotional websites owned and managed by the manufactures were freely available for the general public to access without any restriction. These were <https://www.saxenda.com/> and <https://www.wegovy.com/>. Although these were based in the USA, if the manufacturer wished, it could be easily blocked in the UK or restricted so that the general public could not access it.

The complainant provided a few screenshots of the paid advertisements which they stated showed the promotional activities of these pharmacies through the funding provided by Novo Nordisk.

The complainant stated that it was important that one of the pharmacy chains [Pharmacy Chain B], which was a publicly traded company, was also held accountable for any breaches in behaviour. Ultimately, Pharmacy Chain B was now pushing a campaign to promote its Wegovy service – a service funded by Novo Nordisk which was the manufacturer and beneficiary of

product sales. The complainant's concern was that there would be shortage of stock at some point for Wegovy as well.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 3.4, 5.1, 19.1, 26.1, 26.2, 28.1 and 28.2 of the 2021 Code.

RESPONSE

Novo Nordisk submitted that broadly speaking the complainant appeared to have five concerns, as noted below, which were addressed in turn:

- 1 Novo Nordisk UK actively promoted Saxenda in the UK, despite known and ongoing supply shortages.
- 2 Novo Nordisk UK sponsored a number of pharmacy chains to set up weight management clinics, and provided free stock to grow the market, while supply issues were ongoing.
- 3 Sponsorship provided by Novo Nordisk UK to a number of pharmacy chains was an alleged inducement to prescribe and promoted medicines to the public.
- 4 Novo Nordisk UK did not disclose sponsorships as a transfer of value.
- 5 Novo Nordisk UK engaged in promotion to the UK public via US websites.

1 The allegation that Novo Nordisk UK actively promoted Saxenda despite supply issues

Novo Nordisk submitted that there was an ongoing global supply issue with Saxenda (liraglutide 3mg indicated for weight management). This was a global problem for the entire class of Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) and was not limited to Saxenda or Novo Nordisk. It was the result of unprecedented demand for these products worldwide. The manufacturing capacity had been increased and Novo Nordisk had taken appropriate and responsible steps to manage this situation, working in partnership with health authorities, including the UK's health authorities.

Novo Nordisk reported an anticipated intermittent supply challenge in respect of Saxenda to the Department of Health and Social Care (DHSC) on 19 May 2023, noting an anticipated supply exhaustion date of 19 June 2023. At this point, no medicines supply notification (MSN), had been issued by the DHSC.

On 6 July 2023, a briefing was issued to Novo Nordisk UK's field teams to inform them that:

- The DHSC had issued an MSN on 27 June 2023 for all GLP-1 RAs (MSN/2023/061), which discussed the supply issue for the entire class and
- It was anticipated that an MSN specifically for Saxenda would be issued shortly.

That briefing also included a Q&A compiled with a view to supporting stakeholders to manage this issue.

On 16 August 2023, a further briefing was issued to the field teams to inform them that the DHSC had issued an overarching National Patient Safety Alert (NatPSA) for all GLP-1 RAs (NatPSA/2023/008/DHSC) which, amongst other things, directed prescribers not to initiate new patients on GLP-1 RAs. This briefing document instructed field teams that they '**must not drive**

demand for Saxenda' (emphasis in original). At the same time, Novo Nordisk UK distributed a direct healthcare professional communication (DHPC), approved by The Medicines and Healthcare products Regulatory Agency (MHRA) and DHSC, to relevant UK health professionals and other relevant decision makers, informing them of the information contained within NatPSA/2023/008/DHSC.

Throughout the duration of the GLP-1 RA supply issue, Novo Nordisk UK had been in close contact with UK health authorities and with the DHSC and had, at all times, acted with the interests of patients and prescribers in mind. Novo Nordisk strove to support key stakeholders through the continuing supply issues and had taken appropriate measures to ensure that its teams acted appropriately, including by ceasing to promote Saxenda.

Novo Nordisk, therefore, denied the allegation that any act or omission on its part constituted a breach of the Code (including Clauses 2, 3.4 or 5.1).

2 The allegation that Novo Nordisk UK sponsored a number of pharmacy chains to set up weight management clinics, and provided free stock to grow the market, while supply issues were ongoing

Novo Nordisk submitted that in the past, it had provided sponsorship to three national pharmacy chains including Pharmacy Chain A, Pharmacy Chain B and Pharmacy chain C. Novo Nordisk had not provided any sponsorship or other support to the fourth alleged Pharmacy Chain D. Details of these sponsorships were provided in the contracts and copies were provided. In all cases, the sponsorship was provided to support a pre-existing weight management service for the relevant pharmacy chain (including online services), or to help raise awareness of a pre-existing weight management service. Novo Nordisk UK did not provide any sponsorship to aid pharmacies in '*setting up their private weight management service*', as the complainant suggested.

Arrangements with all of the named pharmacy chains were entered into before there was an issue with the supply of Saxenda (with contract commencement dates ranging from July 2020 to August 2022). The main purpose of entering into all of the sponsorship agreements was to ensure that patients had access to weight management services from reputable, well-regulated healthcare organisations. The purpose, therefore, was not a promotional one, and the activities sponsored by Novo Nordisk UK were completed prior to any supply issues with Saxenda arising.

Novo Nordisk UK had ceased providing any new sponsorships in 2023 and this was effected prior to the issue of the Saxenda shortages arising.

At no time had Novo Nordisk UK provided medicine free of cost. As part of commercial arrangements (in line with commonplace practice across the industry), very low-level discount arrangements were agreed with some of these providers. These commercial arrangements were covered by Clause 1.17 of the Code as being '*measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993*'.

Novo Nordisk, therefore, did not consider that any of the sponsorship agreements in this context amounted to a failure to maintain high standards, nor did the arrangements in this context bring the industry into disrepute, and they denied any breach of Clauses 5.1 and 2 in that regard.

3 The allegation that Novo Nordisk UK's sponsorship provided to a number of pharmacy chains was an inducement to prescribe and promoted medicines to the public

Novo Nordisk submitted that each of the sponsorship agreements contained industry-standard provisions stipulating that the funding provided by Novo Nordisk UK would not give rise to any inducement to prescribe, or obligation or incentive to promote Saxenda (whether to the public or at all). In addition, each agreement required both parties to carry out the agreement in compliance with the ABPI Code.

Alleged inducement to prescribe

The intention of all of the sponsorships referred to in Section 2 above was to ensure that patients had access to weight management services from reputable, well-regulated healthcare organisations. Detailed contracts were put in place which in each case included 'anti-inducement' provisions (Clause 4.2 in the agreements with Pharmacy Chain A and Pharmacy Chain B and Clause 3.2 in the agreement with Pharmacy Chain C). There was no intended or actual inducement to prescribe associated with these sponsorships.

However, with hindsight, Novo Nordisk could recognise that the wording in the 'Background' clause of the agreements with Pharmacy Chain A and Pharmacy Chain B was somewhat ambiguous (in particular, Sections B-D) and might create an inaccurate impression that the provision of sponsorship was linked to the use of Saxenda. Novo Nordisk considered that this wording amounted to a failure to maintain high standards, contrary to the requirements of Clause 5.1. There was, however, no evidence of an intent to induce prescriptions of Saxenda or of any actual inducement ('A') and Novo Nordisk did not consider that this wording would reduce confidence in or bring the industry into disrepute. Novo Nordisk, therefore, denied any breach of Clause 2 in this regard.

Alleged promotion to the public

Novo Nordisk did not agree that the above-mentioned sponsorship activities amounted to promotion to the public.

As noted in the 'Background' of each of the agreements with the pharmacy chains referred to above, the intention of the sponsorships was that the activities in question were to be conducted strictly at arm's-length from Novo Nordisk UK. However, in addition to the sponsorship, each agreement also required the provision to Novo Nordisk UK of certain reports on the progress or outcome of the sponsored activities. Having considered a case completed on 30 March 2023 (Case AUTH/3629/4/22), Novo Nordisk now understood that the contractual requirement for each pharmacy chain to provide these reports might have inadvertently compromised the arms-length arrangement.

Given that at the time Novo Nordisk UK considered that each sponsorship was at arms-length, they did not request for review copies of the material produced as a result of the sponsorships. The contracts in each case did require the third-party to submit to Novo Nordisk UK any materials developed as part of the sponsorship which made reference to their medicines for a medical and factual accuracy review. To the best of Novo Nordisk UK's knowledge, no materials intended for the public were published that referred to Novo Nordisk UK medicines.

4 The allegation that Novo Nordisk did not disclose sponsorships as a transfer of value

Novo Nordisk submitted that the complainant had alleged that none of the transfers of value associated with these sponsorship activities '*have been declared*'. The sponsorship activities in respect of this allegation for both Pharmacy Chain B and Pharmacy Chain C were disclosed on the Disclosure UK portal in full in 2022.

Unfortunately, as a result of an inadvertent oversight, Pharmacy Chain A was not appropriately tagged in Novo Nordisk's finance system as a healthcare organisation and, as a result, the sponsorship for Pharmacy Chain A was not disclosed as a part of the Novo Nordisk UK disclosure process for 2022. This sponsorship was being re-submitted to be included in the 2022 Disclosure UK Portal.

5 The allegation that Novo Nordisk UK engaged in promotion to the public in the UK via US websites

Novo Nordisk submitted that the complainant also referred to Novo Nordisk websites that were '*freely available for the public to access without any restriction*', specifically www.saxenda.com and www.wegovy.com. Both of these websites were originated by Novo Nordisk Inc. in the US and were targeted at a US audience with no input from Novo Nordisk in the UK. Both websites clearly referenced 'Novo Nordisk Inc.' in the footnotes along with the US-registered address. Further, Novo Nordisk UK did not direct readers to either website.

Novo Nordisk, therefore, considered that there was no UK nexus to these websites and the allegation fell outside the scope of the Code.

In response to a request for further information from the Panel Novo Nordisk stated that in relation to the matter of free stock, there appeared to have been a misunderstanding. The reference in its original response to "...very low-level discount arrangements..." was provided in order to be fully transparent to the complainant's allegation that it had provided free stock to pharmacy chains. The discounts referred to were commercial agreements unrelated to and independent from any sponsorship that may have been provided to certain pharmacy chains. This in turn was why it stated that such discounting arrangements, in accordance with Clause 1.17, fell outside the definition of promotion, as measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993.

As requested, Novo Nordisk provided copies of relevant contracts which pre-date those already provided and constituted the initial sponsorship agreements with two of the pharmacy groups. These further two contracts concerned support for weight management services at Pharmacy Chain C and Pharmacy Chain B; Novo Nordisk stated that it was important to note that both Pharmacy Chain C and Pharmacy Chain B had long established weight management services providing Orlistat for many years and indeed other weight management interventions (including OTC products) and both had undertaken to enhance their weight management services based on in-creased demand by patients.

PANEL RULING

This case concerned numerous allegations including Novo Nordisk actively promoting Saxenda despite supply issues, its provision of free stock to pharmacy chains and funding to promote medicines to the public which had not been declared; the complainant further alleged that Novo Nordisk engaged in promotion to the public through its websites in the US. The Panel set out its rulings below.

Supply issues

In relation to the allegation that Novo Nordisk failed to ensure sufficient supply, especially when it actively promoted Saxenda and continued to do so, the Panel noted Novo Nordisk's submission that there was an ongoing supply issue with Saxenda which was a global problem for the entire class of Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs), and was not limited to Saxenda or Novo Nordisk, and was the result of unprecedented global demand for these products. The manufacturing capacity had been increased and Novo Nordisk stated that it had taken appropriate and responsible steps to manage this situation, working in partnership with health authorities. The lack of supply experienced for GLP-1RAs, including Saxenda, was not in itself a Code issue, companies involved would be in contact and discussion with the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) in this regard.

The Panel noted that the complainant linked the alleged failure to ensure supply of Saxenda with unspecified promotional activity and therefore considered that the matter fell within the scope of the Code. The Panel noted that the complainant had not provided detailed reasons to support their view but appeared to be concerned about the overarching principle of promotional activity whilst there were supply problems and referred to the sponsorship of weight loss clinics.

In this regard, the Panel noted Novo Nordisk's submission about its interactions with health authorities and staff briefing including that its field force briefing stated that the Department of Health and Social Care had issued an overarching National Patient Safety Alert for all GLP-1 RAs which, amongst other things, directed prescribers not to initiate new patients on GLP-1 RAs. This briefing document instructed commercial and medical field teams that they 'must not drive demand for Saxenda' and 'must not engage in market development activities for Saxenda'.

The Panel noted that whilst there was no prohibition in the Code regarding the promotion of medicines whilst there were supply difficulties, companies nonetheless had to maintain high standards. The Panel noted Novo Nordisk's submission that arrangements (in the form of sponsorship contracts) with the pharmacy chains were entered into before there was an issue with the supply of Saxenda. The Panel noted that the complainant bore the burden of proof and considered that the complainant had not established that general promotional activity, in the context of supply issues, was such that high standards had not been maintained; **no breach of Clause 5.1 was ruled accordingly.**

Free stock

The Panel noted the allegation that Novo Nordisk was supplying commercially available products free of cost, which enabled these businesses to provide Saxenda at artificially low prices, grow the market at an unnaturally fast pace and thus increase sales of Saxenda and the number of patients accessing the medication, and that this must have been a factor contributing to the shortage for which the manufacturer should be held accountable. The Panel noted Novo Nordisk's submission that at no time had it provided medicine free of cost and that the discounts

referred to were part of commercial contracts unrelated to and independent from any sponsorship that may have been provided to certain pharmacy chains.

The Panel noted that Clause 1.17 stated that promotion did not include '*measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993*'. The Panel noted that the contracts provided solely related to sponsorship; they did not refer to the cost of the medicine or any related discounts and further noted Novo Nordisk's submission that discounts were independent from any sponsorship. The Panel noted that the complainant bore the burden of proof and that the allegation, in this regard, was limited to the provision of commercially available products free of charge. Insofar as the allegation related to medicines, there was no evidence before the Panel to establish that medicines had been provided free of charge, to grow the market at an unnaturally fast rate or as an inducement, and on this basis the complainant had not established that high standards had not been maintained; **the Panel ruled no breach of Clause 5.1 accordingly.**

Contracts and inducement

The Panel noted that the complainant had raised a number of concerns about the sponsorship arrangements including that Novo Nordisk had paid significant amounts of money in the form of sponsorship to large national pharmacy chains which had online prescribing activities the purpose of which was to aid them in setting up their private weight management service. The complainant noted that such sponsorship must be non-promotional and stated that the manufacturer should not have a promotional or commercial incentive when sponsoring third party organisations, especially when they should have been fully aware that they were not able to continue to supply the medication. The Panel noted that Novo Nordisk interpreted the complainant's general comments as an alleged inducement to prescribe.

The Panel noted that the sponsorship contracts with three national pharmacy chains were at issue: Pharmacy Chain B (contracts: November 2021 and August 2022), Pharmacy Chain A (contract: July 2022) and Pharmacy Chain C (contracts: July 2020 and August 2022). The Panel noted that the 2021 Code applied to the contracts, save the Pharmacy Chain C contract dated July 2020 to which the 2019 Code applied. Novo Nordisk submitted it had not provided any sponsorship funding to Pharmacy Chain D contrary to the complainant's allegation.

The Panel noted that Novo Nordisk consistently referred to the arrangements as sponsorship. The Panel noted that sponsorship was defined in Clause 1.22 of the 2021 Code as a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity performed, organised, created etc by certain organisations. Whether a pharmaceutical company was responsible for the sponsored materials/activities would depend on the arrangements set out in the sponsorship contracts. The Panel noted it was an established principle that companies could sponsor materials and activities and not be responsible for them under the Code so long as the sponsorship was strictly at arms' length.

The Panel noted each contract referred to 'certain limited support' being provided to the pharmacy chains 'as part of a strictly arm's length arrangement'.

The Panel noted the contract for Pharmacy Chain C 2020 appeared to be contrary to Novo Nordisk's submission that in all cases, the sponsorship was provided to support or raise awareness of a **pre-existing** (emphasis added) weight management service. In this regard, the

Panel noted the Background section of the initial sponsorship contract with Pharmacy Chain C dated 2020 stated 'as part of a **new offering** (emphasis added), Pharmacy Chain C will be providing a Medicated Weight Loss Programme to its customers'; Schedule 1 of the contract included that '[Pharmacy Chain C] shall establish, implement and maintain the Programme'. Section 4.3 of the contract stated that 'For the avoidance of doubt the parties acknowledge that the programme funding does not fully fund the programme but is intended to partially fund the programme'.

The Panel noted that the sponsorship contracts covered a range of activities and materials and considered that companies should be clear at the outset whether, and the extent to which, they were responsible for such activities and materials and how each material/activity was classified under the Code and whether the arrangements withstood public scrutiny. The Panel noted the sponsorship contracts for the pharmacy groups included the provision of reports to Novo Nordisk (more detail later) and:

- The 2021 contract with Pharmacy Chain B included financial support for i) the marketing of the Weight Loss Service via Google 'pay per click' ii) additional information about weight loss to be provided on the Pharmacy Chain B Health Hub 'tile' that details the Weight Loss Service and iii) an education guide for its pharmacists.
- The 2022 contract with Pharmacy Chain B included financial support for the marketing of the Weight Loss Service via Google 'pay per click'
- The 2020 contract with Pharmacy Chain C included financial support for the development of the Medicated Weight Loss programme, patient coaching app and training video. The contract also included the provision free of charge, of needles (1 month's supply per month), sharps bins (1 per patient every two months) and travel wallets (1 per patient).
- The 2022 contract with Pharmacy Chain C included financial support for a photoshoot (for the service's marketing materials), a BMI calculator and advice tool on the Pharmacy Chain C website, video series and flyers to be added to customer support packs. The 2022 contract was limited to the provision of a free travel wallet per patient.
- The 2022 contract with Pharmacy Chain A was the provision of funding for an awareness campaign (emails and announcements of the service availability), education and training for Pharmacy Chain A prescribers (for which Novo Nordisk would provide medical training sessions), and an improving patient outcome and adherence project. The contract also included the provision of NovoTwist needles and travel wallets free of charge to Pharmacy Chain A.

The Panel noted that each of the contracts required the pharmacy groups to submit reports to Novo Nordisk. The reports varied in the submission timings, weekly, monthly or quarterly, and the level of detail required. Some of the report requirements were quite extensive and others only required high level data. In general, Novo Nordisk wanted to know traffic to the organisation's websites, the conversion and success rates, number of patients starting Saxenda, repeat prescriptions, the duration of treatment, geographical location and number of pens prescribed.

The Panel considered that there was a difference between undertaking due diligence to ensure that funds were used for the intended purpose and the detailed reports which the relevant healthcare organisations were contractually required to provide to Novo Nordisk and for which a separate payment was indicated in certain contracts.

The Panel noted Novo Nordisk's acknowledgement that the reporting requirements had compromised the arms' length arrangement with each provider. The Panel considered that the arms' length relationship was also potentially compromised by Novo Nordisk's ongoing role in certain contracts, such as providing medical training sessions to Pharmacy Chain A prescribers. With regard to the overall arrangements with each pharmacy chain, the Panel agreed that the sponsorships at issue were not strictly arms' length which meant that Novo Nordisk had a responsibility for the sponsored services. The Panel noted that it did not have to determine the extent to which Novo Nordisk was responsible for the sponsored activities/materials. The issue it had to consider, given the complainant's allegation, was whether the arrangements amounted to an inducement.

The Panel noted the broad nature of the complainant's allegations in relation to promotional activity and commercial incentive which Novo Nordisk had interpreted as an alleged inducement to prescribe.

The Panel noted Novo Nordisk's submission that each of the sponsorship contracts contained industry-standard provisions stipulating that the funding would not give rise to any inducement to prescribe, or obligation or incentive to promote Saxenda (whether to the public or at all). In this regard, the Panel noted that whilst such contractual provisions were relevant, all of the arrangements would be taken into consideration when deciding whether the sponsorship contracts amounted to an inducement.

Novo Nordisk had been asked to respond to Clause 19.1 of the 2021 Code which prohibited the supply, offer, or promise of, amongst other things, a pecuniary advantage or benefit to health professionals or other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe. Clause 19.1 applied to individuals, not to arrangements with healthcare organisations and other organisations. The Panel noted that Novo Nordisk had responded to the substance of the inducement allegation in relation to healthcare organisations and therefore the Panel considered this matter under the broad remit of Clause 5.1 of the 2021 Code, and its equivalent Clause 9.1 in the 2019 Code, each required that high standards must be maintained at all times.

The Panel considered, in principle, it was not unacceptable for pharmaceutical companies to sponsor healthcare organisations, including those in the private sector, in areas where the pharmaceutical company had a commercial interest so long as the arrangements complied with the Code including that they did not constitute an inducement to prescribe. The Panel considered that the external impression was also very important when considering the acceptability of the arrangements particularly in a sensitive area that might attract public interest such as weight loss.

The Panel did not have a copy of the Patient Group Direction (PGD) which was only referred to in the Pharmacy Chain C 2020 contract and did not know whether other injectables were named on it. The complainant had provided little detail. The Panel generally understood that Novo Nordisk's medicine was the only injectable prescription only medicine that would be available at the time on the PGD for weight loss.

The Panel considered that the provision of needles was essential for Saxenda's administration and by providing them free of charge an unavoidable cost associated with the prescription of Saxenda had been defrayed. The Panel noted that the wallets and sharps bins were not essential for the administration of Saxenda but noted that it appeared that Saxenda was the only relevant injectable available at that time. It thus appeared that all of the consumables could only be used or distributed by the weight loss clinics with Novo Nordisk medicines.

The Panel noted that in general terms it was not unacceptable to provide needles, wallets and sharps bins so long as the arrangements complied with the Code. For instance, needles might potentially be provided as part of a package deal, a commercial arrangement whereby the purchase of medicines is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration as set out in the supplementary information to Clause 19.1. Similarly sharp bins and wallets might potentially be provided as items for patient support as set out in Clause 26.3.

The Panel had no details as to whether the unavoidable cost of the needles in particular would have ordinarily been absorbed by the pharmacies or passed on to the customer.

The Panel was concerned about the provision of sharps bins and wallets for use with injectables as an integral part of a sponsorship which was intended to be non-promotional given that Novo Nordisk's medicines for weight loss appeared to be the only injectables at the relevant time and thus the sharp bins and wallets in effect could only be used with Novo Nordisk medicines.

In the Panel's view, the provision of the free of charge consumables to Pharmacy Chain C and Pharmacy Chain A was an integral part of the sponsorship contracts and considered that on balance the defrayment of the unavoidable cost in relation to the acquisition cost of the needles associated with a prescription of Novo Nordisk medicine(s), was therefore an inducement.

The Panel noted that it was required to rule on this matter under Clause 5.1. High standards had not been maintained and the Panel therefore ruled **a breach of Clause 5.1** of the 2021 Code in relation to each of the Pharmacy Chain A and Pharmacy Chain C 2022 contracts and **a breach of Clause 9.1** of the 2019 Code in relation to the Pharmacy Chain C 2020 contract.

In relation to the arrangements with Pharmacy Chain B, the Panel noted the contracts only referred to the provision of funding, no consumables were provided, and in relation to each contract the Panel ruled **no breach of Clause 5.1** in this regard.

Clause 26

The Panel noted the complainant's allegation that funding provided by Novo Nordisk was used to actively and aggressively promote their services and the prescription medicines (through various media and Google-paid advertisements) directly to members of the public, which was illegal. The complainant provided an example of what appeared to be an Internet search showing 4 search results for each of Pharmacy Chain B, one of which was sponsored, and Pharmacy Chain A; there was also one search result for Pharmacy Chain C. The search parameters were not provided. The Panel noted that the website addresses for all 3 pharmacies were similar, bearing the prefix 'onlinedoctor'. The Panel noted that the complainant had provided the initial text of the search results which named prescription only medicines including Saxenda and Wegovy and text referred to their indications for weight loss and their prescription

and/or purchase. The Panel was concerned about the search results noting that Clause 26.1 prohibited the promotion of prescription only medicines by pharmaceutical companies to the public, which reflected UK law.

The Panel noted that each contract contained similar terms requiring the healthcare organisation to comply with relevant laws and regulations (Section 2.3.1 of the Pharmacy Chain C contracts dated 2022 and 2020, Pharmacy Chain A contract dated 2022, and Section 2.4.1 of the Pharmacy Chain B contracts dated 2021 and 2022) and each stated that the healthcare organisation 'shall comply with all Applicable Laws and Good Industry Practice'. Whilst, in the Panel's view, none of the sponsorships were strictly arms' length, each contract set out the healthcare organisation's responsibility for the sponsored activities and further, given that it was not an arms' length relationship, Novo Nordisk had certain responsibilities for the activities and materials under the Code.

The Panel noted that irrespective of the extent of Novo Nordisk's responsibilities, and noting the search results, the Panel did not consider that the complainant had established in relation to either Pharmacy Chain A or Pharmacy Chain C that monies had been paid to 'actively and aggressively promote' the weight loss services and the prescription medicines through various media as alleged. The Panel further noted that the subject matter of the Pharmacy Chain B contracts included sponsorship of Google pay per click. The Panel noted that the search results provided by the complainant included one sponsored Pharmacy Chain B result the visible text of which referred to a weight loss service and 'access to prescription weight loss treatment.' There was no reference to specific medicines. It was unclear whether this was a pay per click search result which was the subject of the sponsorship at issue; the date of the complainant's search and the search engine used were not known. In the Panel's view, the complainant had not established that the Pharmacy Chain B sponsored search result was the subject matter of the sponsorship at issue and whether it was promotional. Noting its comments above, the Panel did not consider the complainant had established that Novo Nordisk had funded or was otherwise responsible for the search results. **No breach of Clauses 26.1 and 26.2 was ruled accordingly.**

Disclosure

In relation to the complainant's allegation that none of the sponsorships were declared, the Panel noted Novo Nordisk's submission that the sponsorship activities for both Pharmacy Chain B and Pharmacy Chain C were disclosed on the Disclosure UK portal in full in 2022. The Panel was concerned that Novo Nordisk's admission on this point was unclear in relation to the 2020 and 2022 Pharmacy Chain C contracts and the 2022 Pharmacy Chain B contract given the requirement that the disclosures were required in the first 6 months of the calendar year following that in which the payments were made, 2021 and 2023 respectively.

Nonetheless, the Panel noted the complainant's narrow allegation on which the Panel had to rule was that none of the sponsorships were declared. The Panel noted that Clause 28.1 required the annual publication of certain transfers of value and Clause 28.2 described the categories of transfers of value that fell within Clause 28.1. Failure to disclose a transfer of value described in Clause 28.2 was therefore a breach of Clause 28.1. **The Panel ruled no breaches of Clause 28.1 in relation to transfers of value to Pharmacy Chain B and Pharmacy Chain C** in relation to the allegation that 'none' of the transfers had been declared as it appeared that certain transfers of value had been disclosed in 2022. Noting its comments above, the Panel made no ruling in relation to Clause 28.2.

In relation to transfers of value to Pharmacy Chain A and the Pharmacy Chain A contract dated July 2022, the Panel noted Novo Nordisk's submission that as a result of an inadvertent oversight, Pharmacy Chain A was not appropriately tagged in its finance system as a healthcare organisation and therefore, as a result, the sponsorship was not disclosed as a part of the Novo Nordisk UK disclosure process for 2022. This sponsorship was being re-submitted to be included in the 2022 Disclosure UK Portal. In this regard, the Panel noted that whilst Pharmacy Chain A, a supermarket, was different in nature to Pharmacy Chain B and Pharmacy Chain C, the definition of a healthcare organisation at Clause 1.8 of the Code included amongst other things an organisation through which one or more health professionals or other relevant decision makers provides services. The Panel noted that the background section to the contract stated that Pharmacy Chain A hosted an online doctor service, the Pharmacy Chain A Online Doctor which included a weight loss service which the Panel considered satisfied the definition of a healthcare organisation at Clause 1.8 of the Code. Noting Novo Nordisk's failure to disclose the transfer of values to Pharmacy Chain A, the Panel **ruled a breach of Clause 28.1** of the Code. The Panel made no ruling in relation to Clause 28.2.

US websites

The Panel noted the allegation that Novo Nordisk engaged in promotion to the public in the UK via US websites and referred specifically to www.saxenda.com and www.wegovy.com, of which the former appeared in the search results provided by the complainant. The Panel noted Novo Nordisk's submission that both of these websites originated by Novo Nordisk Inc. in the US and were targeted at a US audience with no input from Novo Nordisk in the UK. Both websites clearly referenced "Novo Nordisk Inc." in the footnotes along with the US registered address and further, Novo Nordisk UK did not direct readers to either website. The Panel noted Novo Nordisk did not respond to the complainant's point that although these were based in the US, if the manufacturer wished, they could be easily blocked in the UK or restricted so that the general public could not access it.

The Panel noted that Clause 1.2 of the Code stated that promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code if it was placed there by a UK company, with its authority or an affiliate of a UK company and it makes specific reference to the availability or use of the medicine in the UK. Taking into account Novo Nordisk's response, the Panel did not consider that the complainant had established that either website came within the scope of the UK Code as set out in Clause 1.2 and therefore **ruled no breach of Clause 26.1 accordingly**.

Clause 3.4

The Panel noted that the Case Preparation Manager had cited Clause 3.4 which required companies to comply with all applicable codes, laws and regulations to which they are subject. The Panel noted its comments above regarding the reports and medical training and that no information was before the Panel to establish the compliance or otherwise of these activities. The Panel queried whether the complainant had made a broad overarching allegation on this point. **No breach of Clause 3.4 was ruled.**

Clause 2

The Panel had broad concerns about the arrangements. Noting its rulings and comments above, the Panel considered that the matters at issue were of serious concern bearing in mind the heightened public interest in and sensitivities around weight loss medication, and the particular importance in ensuring that the arrangements withstood public scrutiny, were robust, transparent and complied with the Code. In this regard, the Panel considered that the arrangements including Novo Nordisk's initial view that the arrangements were at arms' length demonstrated a very poor understanding of the Code.

The Panel noted its ruling of a breach of high standards in relation to inducement and the Pharmacy Chain A 2022 and Pharmacy Chain C 2022 and 2020 contracts, and its ruling of a breach of Clause 28.1 in relation to transfers of value and Pharmacy Chain A. The Panel noted that inducements were listed as activities likely to be in breach of Clause 2 in the relevant supplementary information to that Clause. The Panel therefore **ruled a breach of Clause 2 of the 2019 and 2021 Codes in relation to the Pharmacy Chain A and Pharmacy Chain C contracts.**

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During its consideration of this case the Panel had a number of concerns about the sponsorship contracts. The Panel queried whether sponsorship was the appropriate arrangement. It is imperative for companies to ensure that each activity or material is looked at in isolation and the most appropriate classification for each is determined, especially noting the robust compliance safeguards in the Code for different classifications. Failure to conduct due diligence in this regard could mean that companies miss vital requirements including, but not limited to, legal requirements such as pharmacovigilance. The Panel considered that these safeguards were particularly important in a therapeutic area of public interest and where the company had a commercial interest and was interacting with and/or contributing to the establishment of private weight loss clinics and/or online services. The impression created by the arrangements should be borne in mind.

The Panel noted that it did not have sight of all the materials/items etc that were the subject of the sponsorship including materials provided to health professionals and patients but noted the importance of ensuring that their provision complied with the Code and relevant instructions were given to ensure compliance.

The Panel further noted that transparency and a declaration of sponsorship was important. The Panel considered that the declarations should appear on all materials/activities which were the subject of the sponsorship irrespective of whether they related to the product, defined as Saxenda in the contract. The Panel was concerned about the failure to deal with this matter in the contract to ensure good governance.

The Panel noted its comments above in relation to Novo Nordisk's submission regarding disclosure of the 2022 data. It was important that companies' submissions were clear and accurate, and any admissions were sufficiently detailed such that the nature of the admission and its seriousness was clear. The Panel noted that there had been separate cases completed and ongoing cases regarding Novo Nordisk and disclosure. The Panel further noted that Novo Nordisk was under audit since 2022, in general companies under audit had heightened diligence on Code responsibilities, the lack of clarity with respect to disclosure including miscategorising Pharmacy Chain A during this time was a concern. The Panel noted that the

failure to disclose ToVs to HCOs was the subject of other cases which had been before the Appeal Board for consideration as part of the audit process.

Complaint received **6 September 2023**

Case completed **12 August 2024**