INTERIM CASE REPORT

An interim case report has been published in this case as the final report was delayed because the Code of Practice Appeal Board reported the company to the ABPI Board which required an audit of Novo Nordisk's procedures in relation to the Code (Paragraph 12.2 of the Constitution and Procedure refers) following which the ABPI Board decided to suspend Novo Nordisk from membership of the ABPI for a period of 2 years and required further audits.

CASE AUTH/3525/6/21

COMPLAINANT v NOVO NORDISK

Concerns about sponsored courses offered on LinkedIn

A complainant who described him/herself as a concerned UK health professional provided a screenshot of a LinkedIn post by a provider of clinical training to health professionals, which contained an image of what appeared to be an overweight female on her mobile phone holding a drink, sat on a bench in a park, and stated:

> **'With #obesity affecting around 1 in 4 #adults in the #UK, is your #pharmacy offering a #weight management service? We have funding to get you started if not! Join us Sunday morning for a FREE #webinar to start your journey. Our #nurse will guide you all the way so you are not alone in your setting up. We will #walkthewalk with you [link]?'**

The complainant stated that the post linked to the training provider's webpage which was headed Free Weight Management Course (WEBINAR + PGD [patient group direction]).

The complainant alleged that it was a Novo Nordisk sponsored free weight management course, which meant that the meeting took place on behalf of Novo Nordisk. The website stated that Novo Nordisk had reviewed all the materials for accuracy.

The complainant drew attention to one of the facets of the training which would cover GLP1-RA in the treatment of obesity, which was the only treatment option mentioned and that Novo Nordisk was at the time the only company that had a GLP-RA available for the treatment of obesity.

The complainant alleged that the LinkedIn post did not make clear Novo Nordisk's involvement, nor stated whether it was a promotional or non-promotional meeting; given that the course was for a therapy area, Novo Nordisk was involved in, and ended up giving, a PGD to ensure that even non-prescribers could indirectly prescribe its product, this appeared to be promotional.

The complainant stated that the PGD given was part of what Novo Nordisk was offering individual health professionals. This had a value and it was being given to individuals for their own personal benefit to run private clinics which was bribing health professionals with an inducement to prescribe.

The complainant noted that on the website the course had been run several times, so there was a large number of health professionals who had been offered this by Novo Nordisk.

The complainant alleged that the LinkedIn post did not appear to have been approved by Novo Nordisk, nor did the website where the material was held. There were no overt links to prescribing information in either place, although the website did mention the class of treatments that was being promoted.

The detailed response from Novo Nordisk is given below.

The Panel noted Novo Nordisk's submission that the training provider had been providing training courses on obesity and weight management services since February 2019 and had offered more extensive training on obesity and weight management (including Saxenda) from June 2019; the training provider sought sponsorship from Novo Nordisk to support the training provision at the beginning of 2020. The Panel noted Novo Nordisk's submission that it had agreed to provide sponsorship to ensure that health professionals would receive training from a reputable provider. The sponsorship provided was, according to Novo Nordisk, for the period from February 2020 to December 2021 to support the cost per attendee for a training course for health professionals about obesity and providing a 'how to provide a weight management service', as a webinar or an e-learning module, and the cost of provision of a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

The Panel noted Novo Nordisk's submission that it had supported both activities (training course and PGD) at arm's length and had no influence on the content of the training other than to check the accuracy of the information in the appropriate part of the training slides. The content of the training course had been created by and was owned by the training provider. The PGD for Saxenda had been prepared by another third party, a company that provided clinical services to pharmacists but was offered by the training provider.

The Panel noted that the Medical Weight Management + PGD webinar slides provided by Novo Nordisk, in a slide titled 'medical weight management', discussed three pharmacological treatments, namely: orlistat (brand names: Alli, Xenical, Beacita) which the speaker notes stated could be bought over-the-counter and had very common gastrointestinal side-effects which caused problems with adherence; naltrexone/bupropion (Mysimba) which, according to the speaker notes, was contraindicated for patients with hypertension and due to severity of potential side-effects, was stated as being 'a riskier drug'. It was noted that it was rarely prescribed in the NHS, but it was possible to get a PGD to provide this in a private weight management clinic or pharmacy; and liraglutide (brand name Saxenda); no side-effects were included

in the speaker notes for Saxenda on this slide and it was stated that Saxenda could be provided by an appropriate health professional with a valid PGD.

The Panel noted that the following slide was titled 'cross-trial comparison'. Whilst the slide stated that 'variance in study methods and design mean that cross-trial comparisons should not be relied upon for accuracy', the Panel noted that the speaker notes stated that the results suggested that liraglutide might have the best efficacy of the three and that whilst naltrexone/bupropion had similar efficacy and might be effective in a certain subset of people, it was rarely prescribed due to its potential psychoactive effects.

The Panel further noted that module 3 of the webinar, which consisted of 21 slides, focussed on the role of human endogenous GLP-1 and how GLP-1 analogues worked to suppress appetite focussing on Saxenda, the evidence for the use of liraglutide (Saxenda) 3mg to treat obesity and maintain weight loss (The SCALE study), the indications, licensing, summary of product characteristics (SPC) information and PGD directives; and the administration, titration, dosing, safety reporting and storage of Saxenda. None of the other two treatment options were covered in similar detail.

The fourth module of the webinar titled 'Providing a Weight Management Service' included in the speaker notes that this final module would cover, inter alia, how to talk to patients about obesity, and assess eligibility for Saxenda. The speaker notes for this section included: advice on how to speak to patients about their weight and if suitable for Saxenda to explain how it works and evidence for its use, expected results, that there were side-effects in 40% of people which usually settled within a month, cost of treatment and any extra benefits and the possibility of non-response. The speaker notes further stated that whilst the health professional could recommend Saxenda, the patient needed to make the decision.

The Panel noted that, similarly, the e-learning course material, whilst including reference to Orlistat, Saxenda and Mysimba and their indications and mode of actions, focussed on GLP1-RA (Saxenda) treatment of obesity in more detail.

The Panel noted that it was possible for a company to sponsor materials and activities in which its own products were mentioned and not be liable under the Code for its contents, but only if there had been a strictly arm's length arrangement with no input by the company and no use by the company. It had previously been decided, in relation to material/activities aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

The Panel noted that the sponsorship agreement for the weight management course between the training provider and Novo Nordisk stated, 'Novo Nordisk will be in attendance at training meetings and will be given delegates to follow up'; the third slide of the Medical Weight Management + PGD webinar titled 'Declarations & GDPR' stated 'Novo Nordisk would like to contact you following this course to send further resources and demo equipment, and to support and facilitate setting up a weight management service. Please indicate if you consent to your data being shared with Novo Nordisk.

Your contact details will not be shared with any other party or used for any other purpose'.

According to the contract, signed February 2020, Novo Nordisk would be recognised as the 'official sponsor' of the weight management course in question and it appeared to the Panel that Novo Nordisk was the only sponsor. Furthermore, the Panel noted that the contract had stipulated the sponsorship declaration wording which stated, *inter alia*, that Novo Nordisk had reviewed the training materials used on the course for medical and factual accuracy. In the Panel's view, the company would have had a clear idea of what would be covered before deciding whether or not to fund the project. The Panel thus considered that Novo Nordisk would have been aware that Saxenda would be covered positively within the course, including being the primary medicinal treatment discussed, particularly considering that it had also agreed to fund the cost of provision of a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service. Noting its comments above, the Panel considered that the course (webinar and e-learning) was, in effect, promotional material for Saxenda for which Novo Nordisk was responsible.

The Panel noted that the LinkedIn post at issue appeared to have been posted by the training provider. The Panel noted the complainant's concern that the LinkedIn post did not appear to have been approved by Novo Nordisk, nor did the linked website where the material was held.

The Panel noted that whilst the body of the LinkedIn post did not refer to Saxenda, the linked webpage, which formed part of the post, referred to GLP1-RA in the treatment of obesity. The Panel noted the complainant's assertion that contemporaneous to the complaint, Novo Nordisk was the only company that had a GLP1-RA available for the treatment of obesity. The Panel noted that it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning a product by name.

On the evidence before it, the Panel considered that the LinkedIn post, which included the linked webpage, promoted Saxenda and had not been certified as required by the Code. High standards had not been maintained in that regard and a breach of the Code was ruled. Novo Nordisk's appeal on this point was unsuccessful.

The Panel considered that the content of the LinkedIn post, which included the linked webpage, constituted the promotion of Saxenda to health professionals without the required prescribing information and thus the Panel ruled a breach of the Code. Novo Nordisk's appeal on this point was unsuccessful.

The Panel noted that there was no declaration stating Novo Nordisk's involvement in the weight management course in the body of the LinkedIn post; readers would have to click on the linked webpage to see any reference to Novo Nordisk. The Panel queried whether the wording of the sponsorship declaration on the linked webpage was sufficient; there was no reference to the PGD being for Saxenda or that Novo Nordisk might be in attendance at meetings and given delegates details to follow up as referred to in the signed contract. Regardless of what was stated in the declaration of sponsorship on the linked webpage, the Panel considered that the requirement for readers of sponsored

material and meetings to be aware at the outset had not been met and breaches of the Code were ruled.

The Panel noted its comments above that the webinar, in effect, promoted Saxenda which Novo Nordisk was responsible for, and considered that Novo Nordisk's involvement in relation to such promotion, including that its medicine would be discussed in detail, was not made sufficiently clear at the outset. Therefore, a breach of the Code was ruled. Novo Nordisk's appeal on this point was unsuccessful.

The Panel noted Novo Nordisk's submission that a PGD was a written instruction for the sale, supply and/or administration of medicines to groups of patients who might not be individually identified before presentation for treatment. The Panel noted Novo Nordisk's submission that it paid for the cost per attendee for a training course for health professionals about obesity and providing a 'how to provide a weight management service' which, in the Panel's view, promoted Saxenda. In addition, Novo Nordisk paid for a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

The Panel noted that the written agreement stated that 13,000 health professionals were intended to be trained over 2 years on how to set up a weight loss service, with each delegate provided with a 1 year PGD, and that the financial support to be provided by Novo Nordisk had a maximum contract value of £357,500. was over £350,000. The Panel noted Novo Nordisk's submission that as of 1 July 2021, 4,399 health professionals had completed the training and 599 PGDs had been activated (13.6% of attendees on the training).

In the Panel's view, the provision of funding by Novo Nordisk for the PGD was clearly linked to the promotion of Saxenda; the Panel did not consider there could be any intention other than to directly increase the use of Saxenda. Furthermore, the Panel noted that the cost of the provision of the PGD to prescribe Saxenda was given to individual health professionals. Such funding to individual health professionals did not meet the requirements of the Code and was an inducement to prescribe, supply, administer and/or recommend Saxenda and the Panel therefore ruled a breach of the Code. Novo Nordisk's appeal on this point was unsuccessful.

The Panel noted its comments and rulings above and considered that Novo Nordisk had failed to maintain high standards and a breach of the Code was ruled. Novo Nordisk's appeal on this point was unsuccessful.

The Panel considered that the arrangements between Novo Nordisk and the training provider, particularly in relation to the PGD, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled. Novo Nordisk's appeal on this point was unsuccessful.

Following its consideration of Novo Nordisk's appeal, given the gravity of the breaches ruled, the Appeal Board considered whether further sanctions were warranted.

The Appeal Board was very concerned that Novo Nordisk did not recognise that this was a large-scale Saxenda promotional campaign which Novo Nordisk knowingly paid

for and which was disguised. In the Appeal Board's view the gravity of the breaches was compounded by Novo Nordisk's failures to recognise that its own behaviour was not compliant with the Code. Novo Nordisk had apparently failed to recognise that the content of the training it sponsored which focused on its medicine Saxenda was clearly promotional; failed to recognise that the arrangements including attendance of Novo Nordisk representatives at the webinars and their subsequent follow up with delegates meant that it could not be considered an arm's length sponsorship; and failed to recognise that covering the cost of a PGD was a benefit being offered to individual health professionals and amounted to an inducement. The Appeal Board was concerned about the potential impact on patient safety of providing unbalanced information to a wide audience, particularly given that the arena of weight loss was a highly emotional arena, and particularly given the lack of balance of Saxenda's safety profile and side effects when comparing it with its competitors.

The arrangements relating to the breaches showed a wide-ranging lack of understanding of the requirements of the Code and an obfuscation of responsibilities.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, that Novo Nordisk should be publicly reprimanded for its failings and the potential impact on patient safety outlined above.

The Appeal Board considered the remaining sanctions available to it including that it could require an audit of Novo Nordisk.

The Appeal Board's view was that the circumstances were so egregious that a report to the ABPI Board was the only appropriate course of action. Taking all the circumstances into account, the Appeal Board decided that in accordance with Paragraph 12.1 of the Constitution and Procedure, Novo Nordisk should be reported to the ABPI Board.

The Appeal Board noted that under Paragraph 12.2 of the Constitution and Procedure, the ABPI Board could require an audit to assist it in deciding whether further sanctions in the form of suspension or expulsion of a company were required.

The ABPI Board was seriously concerned over the scale of and the nature of the activities which had been ruled in breach of the Code. The ABPI Board was also concerned about what appeared to be inappropriate commercial focus given the content of the training which Novo Nordisk described as independent and at arm's length in its responses to the Panel and Appeal Board. Further the ABPI Board was concerned about the company's compliance culture, Novo Nordisk's internal governance systems and processes, and a perceived naivety and lack of accountability from Novo Nordisk.

The ABPI Board was unanimous that taking no further action would not be appropriate. Nor did the ABPI Board consider that expulsion from membership of the ABPI was warranted at this stage, but this option could be exercised later.

The process by which a member pharmaceutical company might be suspended from the ABPI was covered in the ABPI's Articles of Association, which made it clear that a majority of at least 75% was required for the ABPI Board to decide to suspend a member company.

A majority (but less than 75%) of the ABPI Board members present were minded to immediately suspend the company from membership of the ABPI, but ultimately the ABPI Board decided to request that the PMCPA undertake an audit of Novo Nordisk as set out in Paragraph 12.2 of the PMCPA Constitution and Procedure as soon as possible to assist the ABPI Board in understanding the company culture and whether this case was a one-off issue or an indicator of a wider compliance failure.

On consideration of the report of the audit and Novo Nordisk's comments upon it, the ABPI Board would then decide whether any further action was required.

On consideration of the December 2022 audit report and Novo Nordisk's comments on it and the company's presentation the ABPI Board remained seriously concerned over the case and Novo Nordisk's response to it. The audit report had not eased those concerns.

Board members were worried about Novo Nordisk's ability to fix the very serious issues shown up by the case and the audit. Among other concerns, it appeared that only now, after the audit, was the company beginning to put all the necessary compliance structures and processes in place. Board members questioned the seriousness and urgency with which the company was acting, especially considering the essential mission the industry had to protect patients.

ABPI Board members believed that always ensuring patient safety – whilst also protecting the industry's privileged position of being permitted to self-regulate – was of paramount importance. Board members discussed the three options open to them and were unanimous that taking no further action would not be appropriate.

Board members noted the requirements for suspension (Article 9.2 of the ABPI's Articles of Association) and expulsion from membership of the ABPI (Article 9.1.6 of the ABPI's Articles of Association).

The Board wished to understand which sanction would best: protect patient safety; send a strong message about the severity of the breaches in question and the proportionate and appropriately serious response of the ABPI Board according to the responsibilities companies have under self-regulation; and encourage rapid cultural and process change within Novo Nordisk and requested additional clarifying information about the self regulatory and statutory regulatory positions in this regard.

The meeting was adjourned pending the requested information. On receipt of that information, the Board reconvened.

Companies should be capable of complying with self-regulation and that the system should be capable of getting companies back to where they needed to be in terms of compliance

Taking all relevant factors into account, those Board members present and voting unanimously agreed on a final decision: Novo Nordisk would be suspended from the ABPI for two years and that suspension would also be subject to various compulsory conditions imposed by the ABPI Board. The Board required that the company be re-audited in late 2023 and late 2024. The re-audits would be expected to show clear significant improvements and that Novo Nordisk was sustaining that improvement. If

demonstratable progress was evidenced and maintained by the end of the two year suspension, the ABPI Board would be minded to allow Novo Nordisk to resume full engagement with the ABPI. However, if progress was lacking, the ABPI Board reserved the right to take further decisions following the review of either re-audit report. The ABPI Board also required regular updates on the company's progress against its compliance improvement plan and pre-vetting of the company's materials.

The ABPI Board would make a further decision about these arrangement upon consideration of the report of the re-audit in late 2023.

A complainant who described him/herself as a concerned UK health professional provided a screenshot of a LinkedIn post by a provider of clinical training to health professionals, which contained an image of what appeared to be an overweight female on her mobile phone holding a drink, sat on a bench in a park, and stated:

> 'With #obesity affecting around 1 in 4 #adults in the #UK, is your #pharmacy offering a #weight management service? We have funding to get you started if not! Join us Sunday morning for a FREE #webinar to start your journey. Our #nurse will guide you all the way so you are not alone in your setting up. We will #walkthewalk with you [link]?'

The complainant stated that the post linked to the training provider webpage which was headed Free Weight Management Course (WEBINAR + PGD).

The linked webpage stated

> 'Novo Nordisk has provided sponsorship to [the named training provider] to cover the cost of the weight management course fee and provision of the PGD [Patient Group Direction] (if required) for each attendee. Novo Nordisk has had no influence over the training materials used on the course and has reviewed the material for medical and factual accuracy only'.

The linked webpage further stated

> 'This course is for UK-registered health care professionals only. You must be registered with an appropriate regulatory body, with your own registration number/PIN to enrol on this course.
>
> We are unable to enrol pharmacy technicians, healthcare assistants, students, nutritionists, aesthetics practitioners, or other unregistered practitioners at this time, due to strict MHRA regulations relating to the advertising of medicines'.

Beneath the heading 'Course Description', it stated, *inter alia*:

> 'The purpose of this live webinar is to provide you with the knowledge, skills and confidence to offer a safe medical weight management service to your patients/clients.
>
> Please note that the content of this course focuses on the private provision of medicines under a PGD, and these sections may not be relevant to some delegates, such as NHS staff and prescribers.

It will cover:

- Obesity as a chronic disease
- Management of Obesity
- GLP1-RA in the treatment of Obesity
- Benefits of weight management services/clinics.'

Beneath this it stated that the aim was to provide balanced and impartial training and advice to assist attendees in offering a weight management service that safely met the individual needs of patients and clients.

The webpage further stated: 'You will receive your certificate and PGD (if eligible) within 3 working days following attendance of the course'.

The webpage referred to 5 dates in June 2021 that the 90 minute virtual webinar was being held.

Readers were informed that they might also wish to consider the weight management e-learning course + PGD.

COMPLAINT

The complainant alleged that it was a Novo Nordisk sponsored free weight management course, which meant that the meeting took place on behalf of Novo Nordisk. The website stated that Novo Nordisk had reviewed all the materials for accuracy.

The complainant drew attention to one of the facets:

- GLP1-RA in the treatment of Obesity – and stated that this was the only treatment option that was mentioned.

The complainant stated that Novo Nordisk was currently the only company that had a GLP-RA available for the treatment of obesity.

The complainant alleged that the LinkedIn post did not make clear Novo Nordisk's involvement, nor stated whether it was a promotional or non-promotional meeting; given that the course was for a therapy area, Novo Nordisk was involved in, and ended up giving, a PGD to ensure that even non-prescribers could indirectly prescribe its product, this appeared to be promotional.

The complainant stated that the PGD given was part of what Novo Nordisk was offering individual health professionals. This had a value and it was being given to individuals for their own personal benefit – to run private clinics. Ergo this was alleged to be bribing health professionals with an inducement to prescribe.

The complainant noted that on the website the course had been run several times, so there was a large number of health professionals who had been offered this by Novo Nordisk.

The complainant alleged that the LinkedIn post did not appear to have been approved by Novo Nordisk, nor did the website where the material was held. There were no overt links to

prescribing information in either place, although the website did mention the class of treatments that was being promoted.

The complainant was not able to give copies of the training materials that were mentioned or the PGD itself but he/she hoped that given the gravity of this, that the PMCPA would be able to undertake a full review of the whole situation. The complainant hoped that Novo Nordisk, in the spirit of self-regulation, would freely offer these materials given the number of grave issues with what was publicly viewable.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 4.1, 9.1, 9.10, 12.1, 18.1 and 22.4 of the Code.

RESPONSE

Novo Nordisk categorically refuted that it had breached the ABPI Code of Practice.

Novo Nordisk had provided sponsorship to the named training provider to support the following:

- The cost per attendee for a training course for health professionals about obesity and providing a 'how to provide a weight management service', as a webinar or an e-learning module.
- The cost of provision of a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

Novo Nordisk submitted that Saxenda was a prescription-only medicine indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:

- ≥30 kg/m² (obese), or
- ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

The named training provider had been providing clinical training to health professionals. for over 15 years. It had been providing training courses on obesity and weight management services since February 2019. This was as additional training to courses being run about vaccinations. Novo Nordisk was not linked to, or associated with, these training courses.

The training provider had offered more extensive training on obesity and weight management (including Saxenda) from June 2019 and sought sponsorship to support the training provision at the beginning of 2020. Novo Nordisk agreed to provide sponsorship to ensure that health professionals would receive training from a reputable provider about obesity and weight management services. Novo Nordisk had become aware of a small number of weight loss clinics that were providing weight management services without appropriate training. Novo Nordisk had reported these clinics to The Medicines and Healthcare products Regulatory Agency (MHRA) where appropriate. Novo Nordisk had also been in dialogue with the Committee of Advertising Practice (CAP) to support the committee in its work in this area. CAP had recently published an Enforcement Notice, jointly with the MHRA.

The sponsorship provided by Novo Nordisk was for the period from February 2020 to December 2021. As per the sponsorship agreement (copy provided), Novo Nordisk agreed to provide sponsorship to cover the cost of the course fee for up to 13,000 health professionals over a two-year period, and the cost of the provision of a PGD. The funding agreed by Novo Nordisk equated to £13.70 per person. The training provider based the predicted figures of those taking up the training course on their experience in running the training courses on vaccinations. The training provider had received 50 percent of the sponsorship funding to date and confirmed that, as of 1 July 2021, 4,399 health professionals had completed the training February 2020 – May 2021, and 599 PGDs had been activated. This was approximately 13% of attendees on the training.

A PGD was a written instruction for the sale, supply and/or administration of medicines to groups of patients who might not be individually identified before presentation for treatment. Novo Nordisk received detailed external legal advice regarding sponsoring the cost of the purchase of a PGD by health professionals. The advice was very clear in confirming that such an activity, set up in the way Novo Nordisk's sponsorship of the training provider was set up, was compliant.

The PGD for Saxenda offered by the training provider had been prepared by another third party, which was a provider of clinical service packages, primarily to pharmacists. Novo Nordisk had had no input into the PGD and no input into who requested or received the PGD. As explained above, the decision to provide sponsorship for the cost of the purchase of a PGD, as well as training, was made to support the responsible use of Saxenda and not in any way as an inducement to recommend Saxenda. Novo Nordisk denied a breach of Clause 18.1 of the Code.

Novo Nordisk submitted that it had supported both activities at arm's length and had had no influence on the content of the training other than to check the accuracy of the information in the appropriate part of the training slides. The content of the training course had been created by, and was owned by the named training provider. Therefore, Novo Nordisk had not certified the materials, nor did the materials require prescribing information for Saxenda. Novo Nordisk denied a breach of Clause 4.1 of the Code.

The training provider made the LinkedIn post regarding the training; Novo Nordisk was not involved in, or aware of, the post. Novo Nordisk was unable to provide a copy of the post beyond that provided by the complainant. When accessing the website via the link provided within the LinkedIn post, the declaration with regard to Novo Nordisk's involvement was clear and prominent (copy provided). In addition, the training provider's website had a clear statement transparently explaining Novo Nordisk's sponsorship of the e-learning module (copy provided). The website was also very clear that the training was for UK-registered health professionals only. Novo Nordisk had provided a copy of the training materials used by the training provider on the webinar. The sponsorship provided by Novo Nordisk was clearly stated on slide three. Therefore, Novo Nordisk denied breaches of Clauses 9.10, 12.1 or 22.4 of the Code. The training provider also verbally updated all attendees of Novo Nordisk's sponsorship. Novo Nordisk submitted that the activity was fully transparent and fully compliant with the Code. The e-learning module had very similar content to the webinar training (copy provided).

In summary, Novo Nordisk categorically refuted all allegations made by the complainant, and denied breaches of Clauses 4.1, 9.10, 12.1, 18.1, 22.4, 9.1 or 2.

Novo Nordisk asked that the PMCPA clarified what steps it had taken to vet the identity of the complainant(s). Novo Nordisk submitted that it, of course, respected the right of a complainant to remain anonymous, however, it had reason to believe the complaint was malicious. Whistle-blower legislation and the concept of anonymity was very important and were fully supported by Novo Nordisk. However, they could not be used to protect complainants who submitted complaints maliciously and without evidence. Novo Nordisk believed the source of the complaint had arisen from two recent employment tribunal cases. Worryingly, Novo Nordisk believed one of the complainants might be acting in conjunction with his/her current employer, another pharmaceutical company. Novo Nordisk was reviewing the available options regarding contacting the other company to express its concerns.

Novo Nordisk regarded the complaint as being grossly defamatory against it and actionable. It included a totally unfounded allegation that Novo Nordisk had bribed health professionals.

PANEL RULING

The Panel noted Novo Nordisk's submission that the named training provider had been providing training courses on obesity and weight management services since February 2019 and had offered more extensive training on obesity and weight management (including Saxenda) from June 2019; it sought sponsorship from Novo Nordisk to support the training provision at the beginning of 2020. The Panel noted Novo Nordisk's submission that it had agreed to provide sponsorship to ensure that health professionals would receive training from a reputable provider. The sponsorship provided was, according to Novo Nordisk, for the period from February 2020 to December 2021 to support the cost per attendee for a training course for health professionals about obesity and providing a 'how to provide a weight management service', as a webinar or an e-learning module, and the cost of provision of a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

The Panel noted Novo Nordisk's submission that it had supported both activities (training course and PGD) at arm's length and had no influence on the content of the training other than to check the accuracy of the information in the appropriate part of the training slides. The content of the training course had been created by, and was owned by the named training provider. The PGD for Saxenda had been prepared by a company that provided clinical services to pharmacists but was offered by the training provider.

The Panel noted that the Medical Weight Management + PGD webinar slides provided by Novo Nordisk, in a slide titled 'medical weight management', discussed three pharmacological treatments, namely: orlistat (brand names: Alli, Xenical, Beacita) which the speaker notes stated could be bought over-the-counter and had very common gastrointestinal side-effects which caused problems with adherence; naltrexone/bupropion (brand name Mysimba) which, according to the speaker notes, was contraindicated for patients with hypertension and due to severity of potential side-effects, was stated as being 'a riskier drug'. It was noted that it was rarely prescribed in the NHS, but it was possible to get a PGD to provide this in a private weight management clinic or pharmacy; and liraglutide (brand name Saxenda); no side-effects were included in the speaker notes for Saxenda on this slide and it was stated that Saxenda could be provided by an appropriate health professional with a valid PGD.

The Panel noted that the following slide was titled 'cross-trial comparison'. Whilst the slide stated that 'variance in study methods and design mean that cross-trial comparisons should not

be relied upon for accuracy', the Panel noted that the speaker notes stated that the results suggested that liraglutide might have the best efficacy of the three and that whilst naltrexone/bupropion had similar efficacy and might be effective in a certain subset of people, it was rarely prescribed due to its potential psychoactive effects.

The Panel further noted that module 3 of the webinar, which consisted of 21 slides, focussed on the role of human endogenous GLP-1 and how GLP-1 analogues worked to suppress appetite focussing on Saxenda, the evidence for the use of liraglutide (Saxenda) 3mg to treat obesity and maintain weight loss (The SCALE study), the indications, licensing, SPC information and PGD directives; and the administration, titration, dosing, safety reporting and storage of Saxenda. None of the other two treatment options were covered in similar detail.

The fourth module of the webinar titled 'Providing a Weight Management Service' included in the speaker notes that this final module would cover, *inter alia*, how to talk to patients about obesity, and assess eligibility for Saxenda. The speaker notes for this section included: advice on how to speak to patients about their weight and if suitable for Saxenda to explain how it works and evidence for its use, expected results, that there were side-effects in 40% of people which usually settled within a month, cost of treatment and any extra benefits and the possibility of non-response. The speaker notes further stated that whilst the health professional could recommend Saxenda, the patient needed to make the decision.

The Panel noted that, similarly, the e-learning course material, whilst including reference to Orlistat, Saxenda and Mysimba and their indications and mode of actions, focussed on GLP1-RA (Saxenda) treatment of obesity in more detail.

The Panel noted that it was possible for a company to sponsor materials and activities in which its own products were mentioned and not be liable under the Code for its contents, but only if there had been a strictly arm's length arrangement with no input by the company and no use by the company. It had previously been decided, in relation to material/activities aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

In practical terms, the arrangements must be such that there can be no possibility that the pharmaceutical company has been able to exert any influence or control over the final content of the material.

Factors which might mean there had not been a strictly arm's length arrangement would include, but not be restricted to:

- Initiation of the material, or the concept for it, by the pharmaceutical company.
- Influence from the pharmaceutical company on the content/balance/scope of the material.
- Choice/or direct payment of the authors by the pharmaceutical company.
- Influence from the pharmaceutical company on the list of persons to whom the material is sent.

The Panel noted that the sponsorship agreement for the weight management course between the training provider and Novo Nordisk stated, 'Novo Nordisk will be in attendance at training

meetings and will be given delegates to follow up'; the third slide of the Medical Weight Management + PGD webinar titled 'Declarations & GDPR' stated 'Novo Nordisk would like to contact you following this course to send further resources and demo equipment, and to support and facilitate setting up a weight management service. Please indicate if you consent to your data being shared with Novo Nordisk. Your contact details will not be shared with any other party or used for any other purpose'.

According to the contract, signed February 2020, Novo Nordisk would be recognised as the 'official sponsor' of the weight management course in question and it appeared to the Panel that Novo Nordisk was the only sponsor. Furthermore, the Panel noted that the contract had stipulated the sponsorship declaration wording which stated, *inter alia*, that Novo Nordisk had reviewed the training materials used on the course for medical and factual accuracy. In the Panel's view, the company would have had a clear idea of what would be covered before deciding whether or not to fund the project. The Panel thus considered that Novo Nordisk would have been aware that Saxenda would be covered positively within the course, including being the primary medicinal treatment discussed, particularly considering that it had also agreed to fund the cost of provision of a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service. Noting its comments above, the Panel considered that the course (webinar and e-learning) was, in effect, promotional material for Saxenda for which Novo Nordisk was responsible.

The Panel noted that the LinkedIn post at issue appeared to have been posted by the training provider. The Panel noted the complainant's concern that the LinkedIn post did not appear to have been approved by Novo Nordisk, nor did the linked website where the material was held. The case preparation manger had not raised Clause 14 in this regard, so the Panel considered the matter under Clause 9.1.

The Panel noted that whilst the body of the LinkedIn post did not refer to Saxenda, the linked webpage, which formed part of the post, referred to GLP1-RA in the treatment of obesity. The Panel noted the complainant's assertion that contemporaneous to the complaint, Novo Nordisk was the only company that had a GLP1-RA available for the treatment of obesity. The Panel noted that it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning a product by name.

On the evidence before it, the Panel considered that the LinkedIn post, which included the linked webpage, promoted Saxenda and had not been certified as required by the Code. High standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

The Panel considered that the content of the LinkedIn post, which included the linked webpage, constituted the promotion of Saxenda to health professionals without the required prescribing information and thus the Panel ruled a breach of Clause 4.1.

The Panel noted that Clause 9.10 stated, *inter alia*, that material relating to medicines and their uses, whether promotional or not which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that company. The supplementary information stated, *inter alia*, that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. The supplementary information

included that this was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party. Clause 22.4 stated that when meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

The Panel noted that there was no declaration stating Novo Nordisk's involvement in the weight management course in the body of the LinkedIn post; readers would have to click on the linked webpage to see any reference to Novo Nordisk. The Panel queried whether the wording of the sponsorship declaration on the linked webpage was sufficient; there was no reference to the PGD being for Saxenda or that Novo Nordisk might be in attendance at meetings and given delegates details to follow up as referred to in the signed contract. Regardless of what was stated in the declaration of sponsorship on the linked webpage, the Panel considered that the requirement for readers of sponsored material and meetings to be aware at the outset had not been met and a breach of Clauses 9.10 and 22.4 was ruled.

The Panel noted its comments above that the webinar, in effect, promoted Saxenda which Novo Nordisk was responsible for, and considered that Novo Nordisk's involvement in relation to such promotion, including that its medicine would be discussed in detail, was not made sufficiently clear at the outset. Therefore, a breach of Clause 12.1 was ruled.

Clause 18.1 stated 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, subject to the provisions of Clauses 18.2 and 18.3.

The Panel noted the complainant's allegation that the PGD was being given to individuals for their own personal benefit, to run private clinics, and therefore constituted an inducement to prescribe. The Panel noted Novo Nordisk's submission that a PGD was a written instruction for the sale, supply and/or administration of medicines to groups of patients who might not be individually identified before presentation for treatment. The Panel noted Novo Nordisk's submission that it paid for the cost per attendee for a training course for health professionals about obesity and providing a 'how to provide a weight management service' which, in the Panel's view, promoted Saxenda. In addition, Novo Nordisk paid for a Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

The Panel noted that the written agreement stated that 13,000 health professionals were intended to be trained over 2 years on how to set up a weight loss service, with each delegate provided with a 1 year PGD, and that the financial support to be provided by Novo Nordisk had a maximum contract value of £350,500. The Panel noted Novo Nordisk's submission that as of 1 July 2021, 4,399 health professionals had completed the training and 599 PGDs had been activated (13.6% of attendees on the training).

In the Panel's view, the provision of funding by Novo Nordisk for the PGD was clearly linked to the promotion of Saxenda; the Panel did not consider there could be any intention other than to directly increase the use of Saxenda. Furthermore, the Panel noted that the cost of the provision of the PGD to prescribe Saxenda was given to individual health professionals. In the Panel's view, such funding to individual health professionals did not meet the requirements of

Clause 18.1 and was an inducement to prescribe, supply, administer and/or recommend Saxenda and the Panel therefore ruled a breach of Clause 18.1.

The Panel noted its comments and rulings above and considered that Novo Nordisk had failed to maintain high standards and a breach of Clause 9.1 was ruled.

Clause 2 was a sign of particular censure and was reserved for such use; the supplementary information listed activities likely to be in breach of this clause which included inducements to prescribe. The Panel considered that the arrangements between Novo Nordisk and the training provider, particularly in relation to the PGD, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL BY NOVO NORDISK

Novo Nordisk submitted that the purpose of providing sponsorship to the named training provider was to ensure health professionals received training from a reputable provider about obesity and weight management treatments and services, and that they were appropriately trained should they wish to set up their own weight management service. It was Novo Nordisk's position that the sponsorship was provided under an arm's length arrangement as detailed below:

The webinar was an independent educational activity for which the training provider maintained complete control. Novo Nordisk submitted that it did not:

- Initiate the concept for the webinars: the training provider had been providing training on obesity and weight management services since February 2019 and approached Novo Nordisk for sponsorship beginning January 2020.
- Influence the content of the materials used during the webinar: in order to not influence the overall content of the webinar materials Novo Nordisk performed a medical and factual accuracy check of the aspects of the material relating to Saxenda only. This was standard practice when a pharmaceutical company provided sponsorship for materials which included information on their medicines to ensure the information provided was accurate and not inconsistent with the summary of product characteristics (SPC) for the company's medicine.
- Select or pay the authors of the materials used during the webinar.
- Influence who attended the webinar.

Novo Nordisk submitted that it did not consider that the attendance of Novo Nordisk representatives at the webinar, nor the entirely appropriate follow up performed by representatives with delegates who provided consent to be contacted, compromised the arm's length arrangement. The presence of the representatives at the webinar did not affect the already prepared material used at the webinar nor did their presence influence which health professionals chose to attend the webinar. Furthermore, any follow-up that was conducted did not utilise the materials created by the training provider. It was routine industry practice for representatives to be present and/or request permission to follow-up with delegates who attended an event sponsored by a pharmaceutical company. In addition, it was not unusual for a company to be the only sponsor of an event and/or of materials.

Webinar (training course) and the materials used during the webinar

Novo Nordisk submitted that as this was an independently arranged educational webinar sponsored at arm's length, Novo Nordisk was clear that this was not a Novo Nordisk promotional activity for Saxenda, nor could it be considered as disguised promotion of Saxenda. As such there was no requirement, nor would it have been appropriate, for Novo Nordisk to certify the webinar material or the LinkedIn post that was developed entirely independently by a third party for its own purposes. Novo Nordisk disagreed that the content of the LinkedIn post and the linked webpage promoted Saxenda and hence there was no requirement for Saxenda prescribing information to be provided.

Taking all of the above into account Novo Nordisk denied breaches of Clauses 4.1, 9.1 and 12.1.

Patient Group Direction (PGD)

Novo Nordisk submitted that it was not uncommon or inappropriate for PGDs to be provided without cost to relevant health professionals which was made possible by sponsorship from a pharmaceutical company.

Novo Nordisk denied that the sponsorship of the provision of a PGD to those health professionals who actively requested it, following completion of the training course, was for the intention of increasing the use of Saxenda.

Novo Nordisk submitted that it had provided funding directly to the training for the sponsorship of the PGD and training course fee. No individual health professional received any form of payment from Novo Nordisk. The cost of the PGD to a health professional would be £79 if purchased directly from the company that provided clinical services to pharmacists , the group which prepared the PGD. As stated in Novo Nordisk's original response, 4399 health professionals had completed the training between February 2020 and May 2021, and 599 PGDs had been activated. As of 1 July 2021, only 13% of attendees on the training course chose to take up the PGD.

Novo Nordisk submitted that as stated in its initial response, the purpose of Novo Nordisk sponsoring the provision of the PGD was to ensure appropriate use of Saxenda. The sponsorship was never developed as a means to incentivise health professionals to supply Saxenda and this was borne out by the small percentage of health professionals who requested the PGD following completion of the course. This further supported Novo Nordisk's position that the PGD was not offered as a way to increase use of Saxenda, there was no obligation or requirement for a health professional attending the training to take up the PGD. This contradicted the complainant's allegation that it was given to health professionals for their personal benefit to run private clinics.

Novo Nordisk submitted that a PGD gave a strict framework which must be fulfilled before a medicine could be supplied by an appropriate individual health professional. The health professional supplying the medicine through a PGD must be suitably trained and qualified to do this. In order for Saxenda to be supplied to a patient, they must undergo an assessment by the health professional and fulfil all the criteria to ensure it was suitable. Novo Nordisk submitted that Saxenda could be supplied in limited circumstances by those health professionals who took up the provision of the PGD.

Therefore, Novo Nordisk did not agree with the Panel's ruling that the provision of sponsorship to a third party for a training course and provision of a PGD was an inducement to prescribe, supply, administer and/or recommend Saxenda and denied a breach of Clause 18.1.

Novo Nordisk submitted that it was of the clear view that that the arrangements between Novo Nordisk and the training provider, particularly in relation to the PGD, did not bring discredit upon, and reduce confidence in, the pharmaceutical industry and therefore the company denied a breach of Clause 2.

COMPLAINANT COMMENTS

The complainant alleged that Novo Nordisk was approached by a private company that offered to train health professionals on its product, provide a presentation containing a considerable amount of information on its product, would give attending health professionals a gift with a monetary value well in excess of what was allowed under the Code (ie no gifts whatsoever), and would enable Novo Nordisk staff to both attend and have follow up afterwards. This was apparently acceptable because this was supposedly at 'arms length'. The complainant queried how the ability for company staff to attend the event, have its product's data demonstrated, and overtly offer for Novo Nordisk to follow up and help set up a clinic was at 'arm's length'. Apart from an external agency creating the slides and choosing the speakers Novo Nordisk had had involvement throughout this event. The complainant acknowledged that the training had been ongoing since 2019 - so Novo Nordisk was not giving sponsorship for something that it was unaware of; it would have been able to be aware of how prominently its product was to be mentioned; the slides were reviewed internally by Novo Nordisk and apparently the massive prominence of its product did not raise any concerns. Novo Nordisk's products were clearly the main attraction, and the PGD offered was only for Novo Nordisk's product - not for any of the other products that were mentioned. The complainant stated that at least if Novo Nordisk was paying for a gift for all products this would be slightly less reprehensible.

The complainant alleged that this was a classic example of why pharmaceutical companies were responsible for third party agents who were working on their behalf.

The complainant alleged that he/she had received over the years many activities that were said to be supported by an arm's length educational grant by pharmaceutical companies. And without exception these had had no involvement or links to a particular company - let alone product.

The complainant noted that Novo Nordisk's other argument was the 'fact' that other companies were giving out PGDs. The complainant alleged that no evidence of this was given, not even one example, and of course this was at the level of using the argument that since other people were breaking the speed limit somehow meant Novo Nordisk was allowed to as well. In terms of being inappropriate, this appeared to be overlooking the fact that the Code explicitly ruled out giving gifts to health professionals. Merely that a small number of the health professionals had taken the gift was not the issue - even if no health professional had it was the mere fact that a gift with a value of £79 was offered which was in contravention of the Code. The complainant stated that to say that a PGD would do anything but incentivise the prescribing was baffling - what on earth was the purpose of it if not to enable prescriptions in the private clinic that Novo Nordisk offered to set up? Again, the argument that only a small number would be able to make use of it was neither here nor there - no gifts of a value of £79 should

ever be offered to health professionals, and certainly not in such a disguised manner. This wasn't failing to maintain high standards - this was clearly bringing the industry into disrepute.

The complainant alleged that this whole process had now been reviewed by Novo Nordisk three times - once at inception, once for the initial complaint and now finally at appeal. And still at such a senior level there remained the view that this was in keeping with the standards expected in the UK under the Code. The appeal contained no understanding and certainly no remorse as to the activity. The complainant queried if this did not raise questions about the internal processes at a company what did?

APPEAL BOARD RULING

The Appeal Board noted Novo Nordisk's submission that at the beginning of 2020, the named training provider sought sponsorship from Novo Nordisk to support its more extensive training on obesity and weight management (including Saxenda) which it had offered since June 2019. The sponsorship provided to the training provider was for the period from February 2020 to December 2021 to support the cost per attendee for a training course for 13 000 health professionals about obesity and providing a 'how to provide a weight management service', as a webinar or an e-learning module, and the cost of provision of a 1 year Patient Group Direction (PGD) to prescribe Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service.

The Appeal Board noted that the sponsorship agreement between the training provider and Novo Nordisk stated 'Novo Nordisk will be in attendance at training meetings and will be given delegates to follow up' and the third slide of the Medical Weight Management + PGD webinar titled 'Declarations & GDPR' stated 'Novo Nordisk would like to contact you following this course to send further resources and demo equipment, and to support and facilitate setting up a weight management service. Please indicate if you consent to your data being shared with Novo Nordisk..'. The Appeal Board thus disagreed with Novo Nordisk's submission that the arrangements constituted an 'arms length sponsorship'. The Appeal Board further considered that Novo Nordisk would have had a clear idea of what would be covered in the training before deciding whether or not to fund the project.

The Appeal Board noted that the Medical Weight Management + PGD webinar slides provided by Novo Nordisk, in a slide titled 'medical weight management', discussed three pharmacological treatments. Firstly, orlistat (brand names: Alli, Xenical, Beacita) which the speaker notes stated could be bought over-the-counter and had very common gastrointestinal side-effects which caused problems with adherence. Secondly naltrexone/bupropion (Mysimba) which, according to the speaker notes, was contraindicated for patients with hypertension and due to severity of potential side-effects, was stated as being 'a riskier drug'. It was noted that it was rarely prescribed in the NHS, but it was possible to get a PGD to provide this in a private weight management clinic or pharmacy. Thirdly liraglutide (brand name Saxenda). The Appeal Board noted that no side-effects were included in the speaker notes for Saxenda on this slide and it was stated that Saxenda could be provided by an appropriate health professional with a valid PGD.

The following slide was titled 'cross-trial comparison'. Whilst the slide stated that 'variance in study methods and design mean that cross-trial comparisons should not be relied upon for accuracy', the speaker notes stated that the results suggested that liraglutide might have the best efficacy of the three and that whilst naltrexone/bupropion had similar efficacy and might be

effective in a certain subset of people, it was rarely prescribed due to its potential psychoactive effects.

The Appeal Board further noted that module 3 of the webinar, which consisted of 21 slides, focussed on the role of human endogenous GLP-1 and how GLP-1 analogues worked to suppress appetite. The focus was on Saxenda, the evidence for the use of liraglutide (Saxenda) 3mg to treat obesity and maintain weight loss (the SCALE study), the indications, licensing, SPC information and PGD directives; and the administration, titration, dosing, safety reporting and storage of Saxenda. In contrast to this in depth discussion of Saxenda, alternative pharmacological options were only mentioned on 2 slides within the entire webinar.

The fourth module of the webinar titled 'Providing a Weight Management Service' included in the speaker notes that this final module would cover, *inter alia*, how to talk to patients about obesity, and assess eligibility for Saxenda. The speaker notes for this section included: advice on how to speak to patients about their weight and if suitable for Saxenda to explain how it works and evidence for its use, expected results, that there were side-effects in 40% of people which usually settled within a month, cost of treatment and any extra benefits and the possibility of non-response. The Appeal Board further noted that a slide within this module titled 'Pricing and Potential Profit' provided the indicative price of Saxenda 3 pen and 5 pen packs and the typical price of a privately available pack of 5 pens. The speaker notes included examples of businesses already offering weight management services using Saxenda (online only, pharmacy services and private aesthetics and bariatric services) which would highlight to attendees the possible profits.

The Appeal Board noted that similarly, the e-learning course material focussed on GLP1-RA (Saxenda) treatment of obesity in more detail over 38 slides, whilst only referring to the other treatment options Orlistat and Mysimba and their indications and mode of actions on 1 slide. The Appeal Board noted for completeness that Orlistat and Mysimba were referred to on two other slides.

The Appeal Board considered that Novo Nordisk would have been aware that Saxenda would be covered positively within the course, including being the only medicine with substantive product information discussed. The Appeal Board bore in mind that Novo Nordisk had also agreed to fund the cost of provision of a PGD for Saxenda to those health professionals who had completed the course and who wished to offer Saxenda as part of their weight management service. It had previously been decided, in relation to material/activities aimed at health professionals, that the content would be subject to the Code if it was not considered strictly arms-length if it was promotional in nature and/or if the company had used the material for a promotional purpose. On the basis of its findings as summarised above, the Appeal Board considered that the course (webinar and e-learning) was, in effect, promotional material for Saxenda for which Novo Nordisk was responsible.

The Appeal Board considered that Novo Nordisk's involvement in relation to the material was not made sufficiently clear at the outset. The Appeal Board further noted that Novo Nordisk had accepted the Panel's rulings of breaches of Clauses of 9.10 and 22.4 acknowledging that their involvement was not sufficiently clear at the outset. The Appeal Board found that promotion was disguised and upheld the Panel's ruling of a breach of Clause 12.1. The appeal on this point was unsuccessful.

The Appeal Board noted that, at that time, Novo Nordisk was the only company that had a GLP1-RA available for the treatment of obesity. The Appeal Board considered that the LinkedIn post by the training provider, which included the linked the training provider's webpage promoted Saxenda; it described the content of the course as focusing on the private provision of medicines under a PGD and referred to GLP1-RA in the treatment of obesity. The LinkedIn post had not been certified as required by the Code and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful. The required prescribing information had not been provided and the Appeal Board upheld the Panel's ruling of a breach of Clause 4.1. The appeal on this point was unsuccessful.

The Appeal Board noted Novo Nordisk's submission that it had no influence on the content of the training other than to check the accuracy of the information in the appropriate part of the training slides. The Appeal Board noted that Section 3.1.2 of the agreement between the training provider and Novo Nordisk stated that the recipient's obligations included 'it provides such co-operation to Novo Nordisk as reasonably necessary to help Novo Nordisk comply with the requirements of the Code and Regulations'. During the appeal the Appeal Board queried whether certain sections within the webinar complied with the Code and whether they should have been picked up as part of Novo Nordisk's review. Novo Nordisk's responses at the appeal were unclear about what had been reviewed by Novo Nordisk and whether anything had been changed; the reviewer of the material was not present at the appeal and it appeared that the question had not been asked of him/her. At the appeal Novo Nordisk asserted that the review was restricted to checking the factual accuracy of the information on Saxenda. At the appeal Novo Nordisk accepted that the webinar would not have been approved under the Code if it had been material created by Novo Nordisk. This was of serious concern to the Appeal Board as it appeared that Novo Nordisk had knowingly supported an activity that it knew it could not undertake itself.

As part of Novo Nordisk's agreement, it would fund a one year PGD for each delegate who completed the training (Section 1 of the agreement refers). The Appeal Board noted Novo Nordisk's submission that as of 1 July 2021, 4,399 health professionals had completed the training and 599 PGDs had been activated (13.6% of attendees on the training).

In the Appeal Board's view, the provision of funding by Novo Nordisk for the PGD was clearly linked to the promotion of Saxenda; the Appeal Board did not consider that there could be any intention other than to directly increase the use of Saxenda. Furthermore, as Novo Nordisk accepted, the cost of the PGD to a health professional would usually be £79 if purchased directly from the company that provided clinical services to pharmacists. Health professionals who attended the course avoided that cost and had to pay nothing as the cost of the provision of the PGD had been paid by Novo Nordisk. At the appeal Novo Nordisk sought to focus on the lack of direct payments to individual health professionals by Novo Nordisk. In the Appeal Board's view the PGD would clearly constitute a benefit to the individual health professionals receiving it, and it was of great concern that Novo Nordisk did not recognise this. In the Appeal Board's view, such a benefit to individual health professionals did not meet the requirements of Clause 18.1 and was an inducement to prescribe, supply, administer and/or recommend Saxenda. The Appeal Board upheld the Panel's ruling of a breach of Clause 18.1. The appeal on this point was unsuccessful.

On the basis of its findings and rulings as summarised above the Appeal Board considered that Novo Nordisk had failed to maintain high standards and it upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

Novo Nordisk emphasised at appeal that it had identified a small number of clinics that were using Saxenda incorrectly or providing weight loss clinics that were providing weight management services without appropriate training, and they wished to correct that position. The Appeal Board noted that the training provider's webpage, which was part of the LinkedIn post, stated that the aim of the training was to provide balanced and impartial training and advice to assist attendees in offering a weight management service that safely met the individual needs of patients and clients. However, the Appeal Board noted that the target audience for the training was not limited to existing clinics which were providing Saxenda, but was a wide target audience. The Appeal Board was significantly concerned at the intended scale of Novo Nordisk's funding for this programme, having provided funding for 13,000 healthcare professionals to be trained. Against that background the Appeal Board were deeply concerned about the heavily biased nature of the training, which placed undue emphasis on the role of Saxenda in weight management, and the potential for profit from its usage. Given the sensitive and often vulnerable nature of patients seeking healthcare professional support for weight loss, the Appeal Board questioned the patient safety impact of this heavily biased training. At the appeal Novo Nordisk stated that when Novo Nordisk entered into the contract with the training provider in early 2020, Saxenda was yet to be reimbursed through NICE and was predominantly prescribed privately. The Appeal Board determined that the training was in reality focussed on how to set up and profit from a Saxenda weight management service. The lack of fair balance or discussion of established treatment options represented provision of unbalanced and misleading content as to the management of weight. The training provided did not amount to training which was required to set up a Weight Management Service. This in essence was a way to train a large number of UK pharmacists on the prescription of Saxenda for profit, and to pay for their PGD to enable it. This was further apparent from the 4 case studies, all entitled 'Suitable for Saxenda?' with no consideration of other pharmacological options.

Clause 2 was a sign of particular censure and was reserved for such use; the supplementary information listed activities likely to be in breach of this clause which included inducements to prescribe. The Appeal Board considered that all of the arrangements regarding the service between Novo Nordisk and the training provider, particularly in relation to the payment of PGD's for individual health professionals, was such that it brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Given the gravity of the breaches the Appeal Board considered whether further sanctions were warranted.

The Appeal Board was very concerned that Novo Nordisk did not recognise that this was a large-scale Saxenda promotional campaign which Novo Nordisk knowingly paid for and which was disguised. In the Appeal Board's view the gravity of the breaches were compounded by Novo Nordisk's failures to recognise that its own behaviour was not compliant with the Code. Novo Nordisk had apparently failed to recognise that the content of the training it sponsored which focused on its medicine Saxenda was clearly promotional; failed to recognise that the arrangements including attendance of Novo Nordisk representatives at the webinars and their subsequent follow up with delegates meant that it could not be considered an arm's length sponsorship; and failed to recognise that covering the cost of a PGD was a benefit being offered to individual health professionals and amounted to an inducement. The Appeal Board was concerned about the potential impact on patient safety of providing unbalanced

information to a wide audience, particularly given that the arena of weight loss was a highly emotional arena, and particularly given the lack of balance of Saxenda's safety profile and side effects when comparing it with its competitors.

The arrangements relating to the breaches showed a wide-ranging lack of understanding of the requirements of the Code and an obfuscation of responsibilities.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, that Novo Nordisk should be publicly reprimanded for its failings and the potential impact on patient safety outlined above.

The Appeal Board considered the remaining sanctions available to it including that it could require an audit of Novo Nordisk.

The Appeal Board's view was that the circumstances were so egregious that a report to the ABPI Board was the only appropriate course of action. Taking all the circumstances into account, the Appeal Board decided that in accordance with Paragraph 12.1 of the Constitution and Procedure, Novo Nordisk should be reported to the ABPI Board.

The Appeal Board noted that under Paragraph 12.2 of the Constitution and Procedure, the ABPI Board could require an audit to assist it in deciding whether further sanctions in the form of suspension or expulsion of a company was required.

The Appeal Board noted that the case raised issues other than the conduct of Novo Nordisk and considered what options were available with regard to the training provider which was a service provider and not a pharmaceutical company. The training provider's activities were brought into scope of the Code due to the involvement of a pharmaceutical company eg Novo Nordisk's sponsorship. If there was no pharmaceutical company involvement, then it was unlikely that its activities would be covered by the Code. In such circumstances a complaint would likely be referred to the MHRA. The case report when published on the PMCPA website would be available to all including the MHRA.

ABPI BOARD CONSIDERATION OF THE REPORT FROM THE APPEAL BOARD

The ABPI Board was seriously concerned over the scale of and the nature of the activities which had been ruled in breach of the Code. The ABPI Board was also concerned about what appeared to be inappropriate commercial focus given the content of the training which Novo Nordisk described as independent and at arm's length in its responses to the Panel and Appeal Board. Further the ABPI Board was concerned about the company's compliance culture, Novo Nordisk's internal governance systems and processes, and a perceived naivety and lack of accountability from Novo Nordisk.

The ABPI Board discussed the available options. The ABPI Board was unanimous that taking no further action would not be appropriate. Nor did the ABPI Board believe that an expulsion from membership of the ABPI was warranted at this stage, but it was acknowledged that this option could be exercised later.

The process by which a pharmaceutical company might be suspended from membership of the ABPI was covered in the ABPI's Articles of Association, which made it clear that a majority of at least 75% was required for the ABPI Board to decide to suspend a member company.

A majority (but less than 75%) of the ABPI Board members present were minded to immediately suspend the company from membership of the ABPI, but ultimately the ABPI Board decided to request that the PMCPA undertake an audit of Novo Nordisk as soon as possible to assist the ABPI Board in understanding the company culture and whether this case was a one-off issue or an indicator of a wider compliance failure. The outcome of the audit would help the ABPI Board to establish this, which would in turn aid the ABPI Board in making its final decision.

On consideration of the report of the audit and Novo Nordisk's comments upon it, the ABPI Board would then decide whether any further action was required.

ABPI BOARD CONSIDERATION OF THE AUDIT REPORT

On consideration of the December 2022 audit report and Novo Nordisk's comments on it and the company's presentation the ABPI Board remained seriously concerned over the case and Novo Nordisk's response to it. The audit report had not eased those concerns.

Board members were worried about Novo Nordisk's ability to fix the very serious issues shown up by the case and the audit. Among other concerns, it appeared that only now, after the audit, was the company beginning to put all the necessary compliance structures and processes in place. Board members questioned the seriousness and urgency with which the company was acting, especially considering the essential mission the industry had to protect patients.

ABPI Board members believed that always ensuring patient safety – whilst also protecting the industry's privileged position of being permitted to self-regulate – was of paramount importance. Board members discussed the three options open to them and were unanimous that taking no further action would not be appropriate.

Board members noted the requirements for suspension (Article 9.2 of the ABPI's Articles of Association) and expulsion from membership of the ABPI (Article 9.1.6 of the ABPI's Articles of Association).

The Board wished to understand which sanction would best: protect patient safety; send a strong message about the severity of the breaches in question and the proportionate and appropriately serious response of the ABPI Board according to the responsibilities companies have under self-regulation; and encourage rapid cultural and process change within Novo Nordisk and requested additional clarifying information about the self regulatory and statutory regulatory positions in this regard.

The meeting was adjourned pending the requested information. On receipt of that information, the Board reconvened.

Companies should be capable of complying with self-regulation and that the system should be capable of getting companies back to where they needed to be in terms of compliance.

Taking all relevant factors into account, those Board members present and voting unanimously agreed on a final decision: Novo Nordisk would be suspended from the ABPI for two years and that suspension would also be subject to various compulsory conditions imposed by the ABPI

Board. The Board required that the company be re-audited in late 2023 and late 2024. The re-audits would be expected to show clear significant improvements and that Novo Nordisk was sustaining that improvement. If demonstratable progress was evidenced and maintained by the end of the two year suspension, the ABPI Board would be minded to allow Novo Nordisk to resume full engagement with the ABPI. However, if progress was lacking, the ABPI Board reserved the right to take further decisions following the review of either re-audit report. The ABPI Board also required regular updates on the company's progress against its compliance improvement plan and pre-vetting of the company's materials.

The ABPI Board would make a further decision about these arrangements upon consideration of the report of the re-audit in late 2023.

Complaint received	**22 June 2021**
Undertaking to Panel received	**22 June 2022**
Undertaking to Appeal Board received	**12 October 2022**
Appeal Board consideration	**15 September 2022**
ABPI Board consideration	**18 October 2022, (9 March, 14 March 2023)**
Interim case report first published	**30 November 2022**