CASE AUTH/3198/5/19

COMPLAINANT v NOVO NORDISK

Promotion of Saxenda at meetings

A contactable complainant who wished to remain anonymous raised concerns about the activities of Novo Nordisk representatives and the promotion of Saxenda (liraglutide). Saxenda was indicated as an adjunct to a reduced calorie diet and increased physical activity for weight management in adult patients who were obese or overweight with at least one weight-related comorbidity.

The complainant alleged that at a Novo Nordisk sponsored obesity training course that covered Saxenda held at the offices of a named pharmacy on 6 March and others held since, there were numerous activities carried out by Novo Nordisk representatives that were entirely improper and non-compliant.

The complainant alleged that Novo Nordisk representatives had misled health professionals who had attended the series of training meetings and put the public at risk and raised the following issues:

a) **The use of inaccurate and unapproved material used to promote Saxenda by two named Novo Nordisk representatives (representative A) and (representative B) who were the authors of the material)**

b) **Representative A presented during the March meeting using self-created and unapproved material which discussed product side-effects, dosage instructions and advice on how to use the product which differed from the information in the summary of product characteristics (SPC).**

c) **The material was saved in a shared folder and shared nationally to delegates who attended the meetings. Some of the self-made material included advice on how to manage side-effects, patient consent forms and a weight-loss program. Health professionals were using this material as the basis of their weight-loss service.**

d) **Novo Nordisk representatives provided incorrect advice regarding Care Quality Commission (CQC) registration and insurance. If the delegates followed the given advice, they would have conducted a weight-loss service illegally. As per CQC guidance, any weight-loss service where a prescription-only medicine was used should be registered with the CQC. The representatives provided advice contrary to this.**

e) **The complainant was advised that the shared folder had been removed and the organisation had been made aware, yet delegates who attended the meetings had not been informed not to use the unapproved material that was distributed as it was unapproved and potentially misleading. The material was still used by the named pharmacy as part of the series of training meetings.**

f) **What oversight did Novo Nordisk have of the representatives carrying out these meetings? Was the company aware who attended the meetings and what material was being used by these representatives?**

g) **The complainant stated that Novo Nordisk had sponsored the named pharmacy with very significant funding. Why were the sponsors then delivering the course and preparing the material? There should be a clearer distinction.**

In conclusion, the complainant stated that a number of regulatory bodies including the CQC had expressed concerns regarding the inappropriate use of Saxenda and the risks it posed within the aesthetics industry. The last thing expected was that employees of Novo Nordisk would deliver factually incorrect information to health professionals who would then carry out private clinics with patients.

The materials provided by the complainant included a document titled 'Saxenda needles and dose information', drug information on Saxenda and another product (marketed by a different company) including mechanism of action and safety information, patient consent forms, a weight-loss programme follow-up appointment form and information on a weight loss programme.

The detailed response from Novo Nordisk is given below.

The Panel noted Novo Nordisk's submission that the documents provided by the complainant were prepared by the named pharmacy; Novo Nordisk understood that the 'Saxenda Resource Pack' was based on these documents. According to Novo Nordisk representative A, despite his/her initial comment that there was no input from Novo Nordisk into the creation of the 'Resource Pack' materials, submitted that he/she provided limited administrative support including typing/copy-pasting/formatting into a blank Word document (previously referred to by Novo Nordisk as a template) information already contained within a separate document provided to him/her by the health professionals who created the materials for the pharmacy. Novo Nordisk stated that it did not influence the content of the information and acknowledged that the materials were not to the standard it would require had they been Novo Nordisk materials. The Panel had not seen the materials provided to representative A by the health professionals referred to above.

The Panel noted Novo Nordisk's submission that the meeting on 6 March was organised by the named pharmacy who prepared the agenda, organised all the sessions and speakers, and provided any material to attendees. Novo Nordisk sponsored the meeting and representative A presented the Saxenda sessions, save the 'Resource Pack', as requested by the pharmacy. The Panel noted that according to Novo Nordisk the 'Saxenda Resource Pack' was presented by a named health professional at the meeting on 6 March and did not appear to be distributed at the meeting.

The named Panel noted the complainant's statement that the 'Resource Pack' material was saved into a shared folder and shared nationally to delegates who attended these series of meetings. The Panel noted Novo Nordisk's submission that the training events were not a national activity. The Panel noted Novo Nordisk's submission that the pharmacy confirmed that it had provided access to the materials, via a link, to 5

delegates who attended the meeting on 6 March. The Panel noted that according to Novo Nordisk representative B had, despite his/her initial comments, emailed the link to the shared folder containing the 'Resource Pack' materials to a small number of external third parties (three in total from Novo Nordisk's investigation). According to Novo Nordisk the two representatives, the pharmacy and a small number of external third parties had access to the shared folder. This was in addition to the 5 delegates referred to above.

In the Panel's view, Novo Nordisk was responsible for the 'Resource Pack' material as it had created the documents by copying, pasting and formatting the material and had facilitated its availability via the shared folder by emailing a link to a small number of health professionals. The Panel ruled a breach as Novo Nordisk had not certified the material for such use. The Panel noted that the complainant did not detail what exactly in his/her view was inaccurate about the 'Resource Pack' material. It was not for the Panel to infer a complainant's allegations. The Panel therefore ruled no breach of the Code.

The Panel noted that whilst in its view it would be good practice and prudent to follow up with those who had had access to the unapproved 'Resource Pack' material, in the particular circumstances of this case, as noted above, the complainant had not established that the material was inaccurate and based on the narrow allegation the Panel ruled no breach of the Code.

The Panel considered that in creating and distributing unapproved material and failing to provide an accurate description of their involvement in this regard the two representatives had failed to maintain a high standard of ethical conduct and a breach was ruled.

The Panel noted Novo Nordisk's submission that representative A presented a certified presentation 'Obesity Causes, Consequences and Treatment' at the meeting held in March 2019 and therefore ruled no breach of the Code in that regard. The Panel noted that the complainant did not detail how in his/her view the presentation differed from the information in the SPC. It was not for the Panel to infer detailed reasons to support a complainant's allegations. The Panel did not consider that the complainant had established that the presentation was inconsistent with the SPC as alleged and no breach was ruled.

The Panel noted that whilst the named individual at the pharmacy appeared to be confused between not having to be CQC registered to book on the training course and the requirement to be CQC registered to administer Saxenda, it did not consider that there was evidence to show that representative A had provided misleading information that was not capable of substantiation as alleged. The Panel therefore ruled no breach of the Code including Clause 2 this regard.

The Panel noted its comments and rulings above. The Panel did not consider that the complainant had provided evidence that Novo Nordisk had failed to maintain high standards in relation to its oversight of the sponsorship of the obesity training meetings and no breach was ruled.

Whilst the Panel was concerned about the activities of the representatives, noting its comments and rulings above, it did not consider that, overall, the circumstances warranted a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's material and activities. No breach of Clause 2 was ruled.

A contactable complainant who wished to remain anonymous raised concerns about the activities of Novo Nordisk representatives. The complaint was about the promotion of Saxenda (liraglutide). Saxenda was indicated as an adjunct to a reduced calorie diet and increased physical activity for weight management in adult patients who were obese or overweight with at least one weight-related comorbidity.

COMPLAINT

The complainant stated that on 6 March 2019 Novo Nordisk sponsored an obesity training course that covered Saxenda (liraglutide 3mg) at the offices of a named a pharmacy. The complainant alleged that at this training meeting and others held since, there were numerous activities carried out by Novo Nordisk representatives that were entirely improper and non-compliant. The complainant stated that Saxenda was an excellent medicine with benefits when used correctly, however, as was well highlighted, the medicine carried serious risks when used by untrained individuals. The complainant stated that he/she was appalled at the manner in which Saxenda had been marketed by Novo Nordisk at these meetings.

The complainant alleged that Novo Nordisk representatives had misled health professionals who had attended the series of training meetings and put the public at risk. The complainant raised the following issues:

a) The complainant alleged there was both inaccurate and unapproved material used by the two named Novo Nordisk representatives (representative A and representative B) who were the authors of the material. The material was used to promote Saxenda (copy provided).

b) Representative A presented during the meeting using material that the complainant alleged was self-created and unapproved and which discussed product side-effects, dosage instructions and advice on how to use the product. The information differed from the information in the summary of product characteristics (SPC).

c) The material was saved into a shared folder and shared nationally to delegates who attended these series of meetings. Some of the self-made material included advice on how to manage side-effects, patient consent forms and a weight-loss program. Health professionals were using this material as the basis of their weight-loss service. All created on Microsoft Word.

d) Novo Nordisk representatives provided incorrect advice regarding Care Quality Commission (CQC) registration and insurance. If the delegates followed the given advice, they would have conducted a weight-loss service illegally. As per CQC guidance, any weight-loss service where a prescription-only medicine was used should be registered with the CQC. The representatives provided contrary advice.

e) The complainant was advised that the shared folder had been removed and the organisation had been made aware, yet delegates who attended the meetings had not

been contacted and informed not to use the unapproved material that was distributed as it was unapproved and potentially misleading. The material was still used by the pharmacy with their delegates as part of the series of training meetings. Novo Nordisk had a responsibility to carry out retrospective actions in order to manage risks that its product might cause due to potential improper use.

f) The complainant asked what oversight Novo Nordisk had of its representatives carrying out these meetings? Could it confirm which delegates attended the meetings and if they had been followed up by the company to ensure they knew that unapproved material was used during the training meetings. Was Novo Nordisk aware what material was used by these representatives at all?

g) The authors of all the attached documents were Novo Nordisk representatives A and B.

h) The complainant stated that Novo Nordisk had sponsored the pharmacy with very significant funding. Why were the sponsors then delivering the course and preparing the material? The complainant believed there should be a clearer distinction.

In conclusion, the complainant stated that a number of regulatory bodies including the CQC had expressed concerns regarding the inappropriate use of Saxenda and the risks it posed within the aesthetics industry. The last thing expected was that employees of Novo Nordisk would deliver factually incorrect information to health professionals who would then carry out private clinics with patients.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 3.2, 7.2, 7.4, 9.1, 14.1, 14.2, 15.2, 15.9 and 2 of the Code.

RESPONSE

Novo Nordisk submitted that it treated any complaint extremely seriously, and so it had conducted a very thorough investigation and as a result categorically refuted the allegation that it had breached the Code and, in particular, Clauses 2, 3.2, 7.2, 7.4, 9.1, 14.1, 14.2, 15.2 and 15.9.

Novo Nordisk's relationship with the named pharmacy

Novo Nordisk stated that the named pharmacy was a trading name for another organisation. It was a pharmacy and short-line wholesaler which supplied products to private clinics. Novo Nordisk entered into a contractual agreement with it in February 2019, for the following:

1 Novo Nordisk would purchase sales data relating to Saxenda from the pharmacy. This was to provide a clearer picture of obesity clinics/sales of Saxenda through the private market. Novo Nordisk submitted it was a *bona fide* agreement which had been thoroughly checked in respect of all relevant legal and compliance issues.

2 Novo Nordisk would pay for four advertisements for Saxenda in the pharmacy price list.

3 Novo Nordisk had agreed to sponsor six obesity training meetings throughout 2019, organised and run by the pharmacy, on the condition that there was a minimum of ten health professionals attending the training.

Novo Nordisk provided details of the costs of the activities. It had not made any payments at the time of the response, as the agreement was relatively recent. Novo Nordisk confirmed that the sponsorship support would be disclosed on Disclosure UK in 2020, for support given in 2019, in accordance with EFPIA and ABPI Codes.

Obesity training events

Novo Nordisk stated that it had sponsored five training events in 2019 held by the pharmacy. These were held at two locations; two training events at one and three training events at the other.

The training events were organised by the pharmacy, which was in full control of the arrangements. The pharmacy invited relevant health professionals and managed the attendees; it also prepared the agenda, organised all the sessions, any external speakers and provided any relevant materials to the attendees.

Novo Nordisk provided a copy of the agenda provided by the pharmacy to attendees. The named representatives A and B had been invited by the pharmacy to present on the following topics on the agenda; obesity and treatment overview, Saxenda – data and trials, Saxenda mode of action, side-effects and initiation.

At the meeting on 6 March 2019, representative A presented the Saxenda sessions as requested. A health professional presented the other sessions on the agenda. There were six attendees at the training meeting. Representative A used a certified presentation (ref UK19OB00024), 'Obesity Causes, Consequences and Treatment', which covered the three topics on the agenda.

Representative A demonstrated the correct use of the Saxenda injection pens and the needles and showed the patient booklet (ref UK/SA/0616/0068).

In May 2019 the two representatives (A and B) were interviewed separately by Novo Nordisk. Both representatives were categorical that they had not used uncertified material. They were asked directly about the creation of materials and use of a shared folder and categorically denied that Novo Nordisk created materials for use by health professionals or made such a folder available to health professionals.

Representative A stated that all material in question, and attached in the complaint, was prepared by health professionals either from the pharmacy or engaged by the pharmacy to undertake the training. Representative A was clear that there was no input from Novo Nordisk to the creation of these materials.

Notwithstanding that Novo Nordisk was not involved in creating the materials in question, the company ensured that the pharmacy stopped making the materials available to health professionals when it became aware of their existence.

CQC (Care Quality Commission) registration

Novo Nordisk stated that during the investigation interviews, both representatives stated that they were aware that health professionals must undertake training with the CQC and be registered with the CQC before they could provide services in relation to Saxenda. Both were categorically clear that they had never stated or implied that services in respect of Saxenda could be provided without CQC registration.

A copy of an email between representative A and an employee of the pharmacy in February 2019, in which representative A stated that health professionals did not need to be CQC registered to attend the training was provided. This response was absolutely not in relation to the need to be registered to administer Saxenda. Novo Nordisk's view was that this was from where any confusion on this point could have arisen.

In conclusion, Novo Nordisk refuted the claim that its representatives had used uncertified materials whilst taking part in the training events run by the pharmacy, and the allegation that Clauses 2, 3.2, 7.2, 7.4, 9.1, 14.1, 14.2, 15.2 and 15.9 had been breached.

Additional information provided by Novo Nordisk.

The company stated that it had recently come to light that representative A might have had some involvement in the materials produced by the health professionals engaged by the pharmacy. This was contradictory to the information provided by representative A as part of the investigation of the complaint.

Although Novo Nordisk was satisfied that representative A did not create the materials, it had become clear that both representatives facilitated the availability of the pharmacy materials to a small number of external third parties (including short-line wholesalers and pharmacies) via the shared folder.

Upon being re-interviewed, representative A admitted to having provided some limited administrative support by providing a blank Word template to the health professionals who created the materials for the pharmacy, and by formatting some of the documents produced by these health professionals.

Representative B was also re-interviewed and also admitted to having facilitated the availability of the pharmacy materials to a small number of external third parties.

Novo Nordisk submitted that although this information did not change its substantive response above, it was very disappointed to discover that the two representatives had not been fully transparent in their initial interviews.

The representatives did not create or make use of the materials but rather were involved indirectly through facilitating the process; therefore, Novo Nordisk remained clear that it was not in breach of Clauses 7.2, 7.4 and 14.1 nor in breach of Clauses 2, 3.2, 14.2, 15.2 and 15.9.

In response to a request for further information Novo Nordisk confirmed that representative A provided a demonstration on the correct use of Saxenda and showed the patient booklet in the same session of the agenda which covered the three topics: Obesity and treatment overview, Saxenda – data and trials, and Saxenda mode of action, side effects and initiation.

The remaining topics on the agenda were presented by non-Novo Nordisk persons. A named doctor presented on the Saxenda Resource Pack and Starting a Weight Loss Clinic. He/she also participated in a question and answer session. As a sponsor (rather than the organiser) of this meeting, Novo Nordisk was unable to provide additional details on these topics as they were arranged directly by the pharmacy in conjunction with the doctor representatives and Novo Nordisk and was unable to obtain additional information.

With regard to the Resource Pack, Novo Nordisk submitted that it did not appear that it was distributed at the meeting. The pharmacy confirmed via email to representative A that it provided access to the Resource Pack, via a link, to 5 delegates.

Novo Nordisk understood that the Resource Pack consisted of the pharmacy materials, and Novo Nordisk's assumption was that the pack was based on the enclosures provided by the complainant.

Novo Nordisk submitted that it believed representative A provided limited administrative support by typing/copy-pasting into a blank Word document, information already contained within a separate document. This separate document was provided to him/her by the health professionals who created the materials for the pharmacy. Novo Nordisk assumed that some or all of these materials formed the Resource Pack.

Novo Nordisk previously referred to representative A providing a 'blank Word template'. Novo Nordisk wanted to make it clear that this 'template' was simply a blank Word document that representative A pasted information into.

Although the involvement of representative A and representative B was minimal and they did not create the Resource Pack as previously stated by Novo Nordisk, the company was very disappointed to discover that both representatives had not been fully transparent in their initial interviews.

Novo Nordisk believed that the pharmacy materials were those documents provided by the complainant. Representative B emailed the link to the shared folder containing the materials to a small number of external third parties via email (three in total from Novo Nordisk's investigation).

Novo Nordisk believed that representative A, representative B, the pharmacy and a small number of external third parties (referred to above) had access to the shared folder. As it had been deleted, Novo Nordisk was unable to provide information as to how many times documents in the folder were viewed or downloaded. The shared folder was deleted by representative B following an email sent by a Novo Nordisk employee on 15 March 2019. Novo Nordisk had not been able to find written evidence that there was follow up with the small number of health professionals. This might be due to the limited amount of time the link was available to them (three days).

Novo Nordisk submitted that the Obesity Training Events were not a national activity, they only took place in two named locations. Novo Nordisk provided a copy of the Meetings SOP. The training meetings had been agreed as part of the head office planning process and the SOP was followed.

The documents provided by the complainant were prepared by the pharmacy. Novo Nordisk did not influence the content of the information. However, Novo Nordisk acknowledged that the materials were not to the standard it would require had they been Novo Nordisk materials.

Novo Nordisk was unable to find any response from representative A, to the email from an individual employed at the pharmacy dated 21 February which asked representative A, to confirm whether practitioners need to be CQC registered or not to administer the product. Novo Nordisk submitted that representative A, might have telephoned the individual to answer the question, or answered it face to face. Novo Nordisk noted that the response provided by representative A in her email to the individual dated 19 February related to not being required to be CQC registered to attend the training meeting. During the investigation representative A, was adamant that she did not suggest to anyone that Saxenda could be administered by a clinic that was not CQC registered.

PANEL RULING

The Panel noted the complainant's allegation that the two Novo Nordisk representative's had used inaccurate and unapproved material which they had authored to promote Saxenda at a series of obesity training meetings. The Panel noted that whilst the complainant referred to a series of meetings, he/she referred specifically to the meeting held on 6 March. The materials provided by the complainant included a document titled 'Saxenda needles and dose information', information on Saxenda and a product marketed by a different company including mechanism of action and safety information, patient consent forms, a weight-loss programme follow-up appointment form and information on a weight loss programme.

The Panel noted Novo Nordisk's submission that the documents provided by the complainant were prepared by the pharmacy; Novo Nordisk understood that the 'Saxenda Resource Pack' was based on these documents. The Panel noted Novo Nordisk's submission that the two representatives did not create the Resource Pack; their involvement was minimal. The Panel considered that Novo Nordisk's subsequent responses were such that its initial submission about the creation and use of the 'Saxenda Resource Pack' were not a fair reflection of the arrangements. According to Novo Nordisk representative A, despite his/her initial comment that there was no input from Novo Nordisk into the creation of the 'Resource Pack' materials, submitted that he/she provided limited administrative support including typing/copy-pasting/formatting into a blank Word document (previously referred to by Novo Nordisk as a template) information already contained within a separate document provided to him/her by the health professionals who created the materials for the pharmacy. Novo Nordisk stated that it did not influence the content of the information and acknowledged that the materials were not to the standard it would require had they been Novo Nordisk materials. The Panel had not seen the materials provided to representative A by the health professionals referred to above.

The Panel noted Novo Nordisk's submission that the meeting on 6 March was organised by the pharmacy who prepared the agenda, organised all the sessions and speakers, and provided any relevant materials to attendees. Novo Nordisk sponsored the meeting and representative A presented the Saxenda sessions, save the 'Resource Pack', as requested by the pharmacy. The Panel noted that according to Novo Nordisk the 'Saxenda Resource Pack' was presented by a named health professional at the meeting on 6 March and did not appear to be distributed at the meeting.

The Panel noted the complainant's statement that the 'Resource Pack' material was saved into a shared folder and shared nationally to delegates who attended these series of meetings. The Panel noted Novo Nordisk's submission that the training events were not a national activity. The Panel noted Novo Nordisk's submission that the pharmacy confirmed that it had provided access to the materials, via a link, to 5 delegates who attended the meeting on 6 March. The Panel noted that according to Novo Nordisk representative B had, despite his/her initial comments, emailed the link to the shared folder containing the 'Resource Pack' materials to a small number of external third parties via email (three in total from Novo Nordisk's investigation). According to Novo Nordisk the two representatives, the pharmacy and a small number of external third parties had access to the shared folder. This was in addition to the 5 delegates referred to above.

According to the complainant he/she was advised that the shared folder had been removed but delegates who attended the meetings had not been contacted and informed not to use the unapproved material that was distributed as it was potentially misleading.

Novo Nordisk stated that as the shared folder had been deleted on 15 March 2019, it was unable to provide information as to how many times documents in the folder were viewed or downloaded. Novo Nordisk had not been able to find written evidence that there was follow up with the small number of health professionals who had access to it for three days. It was unclear to the Panel whether the three days related to the availability via the emailed link from representative B, or the link provided by the pharmacy to the five delegates that attended the meeting on 6 March or both.

In the Panel's view Novo Nordisk was responsible for the 'Resource Pack' material as it had created the documents by copying, pasting and formatting the material and had facilitated its availability by emailing a link to a small number of health professionals. The Panel noted that Novo Nordisk had not certified the material for such use and a breach of Clause 14.1 was ruled. The Panel noted that the case preparation manager had raised Clause 14.2 which related to the certification of overseas meetings. The Panel did not consider that this clause was relevant in this case and therefore made no rulings in this regard. The Panel noted that the complainant did not detail what exactly in his/her view was inaccurate about the 'Resource Pack' material. It was not for the Panel to infer a complainant's allegations. The Panel therefore ruled no breach of Clause 7.2.

The Panel noted that whilst in its view it would be good practice and prudent to follow up with those who had had access to the unapproved 'Resource Pack' material, in the particular circumstances of this case, as noted above, the complainant had not established that the material was inaccurate and based on the narrow allegation the Panel ruled no breach of Clause 9.1 in this regard.

The Panel noted that Novo Nordisk was very disappointed to discover that both representatives had not been fully transparent in their initial interviews with regard to their involvement in the creation and availability of the materials provided by the complainant. The Panel noted its comments above and considered that in creating and distributing unapproved material and failing to provide an accurate description of their involvement in this regard the two representatives had failed to maintain a high standard of ethical conduct and a breach of Clause 15.2 was ruled.

The Panel noted the complainant's further concern that representative A presented self-created and unapproved material which differed from the information in the summary of product characteristics (SPC). The Panel noted Novo Nordisk's submission that representative A presented a certified presentation (ref UK19OB00024) 'Obesity Causes, Consequences and Treatment' at the training meeting held on 6 March 2019 as requested by the pharmacy. The Panel therefore ruled no breach of Clause 14.1 in relation to the presentation. The Panel noted that the complainant did not detail how in his/her view the presentation differed from the information in the SPC. It was not for the Panel to infer detailed reasons to support a complainant's allegations. The Panel did not consider that the complainant had established that the presentation was inconsistent with the SPC as alleged and no breach of Clause 3.2 was ruled.

The Panel noted the complainant's allegation that Novo Nordisk representatives provided incorrect advice regarding Care Quality Commission (CQC) registration and insurance. The email provided by the complainant which stated '…you do not need to be CQC registered to administer the products, this has been confirmed by the trainers/reps from Novo Nordisk' was sent by the named pharmacy training manager on 21 February. The Panel noted from the email correspondence provided by Novo Nordisk that representative A informed a named individual at the pharmacy on 19 February that health professionals did not need to be CQC registered in order to book onto the training course. The same person emailed representative A on 21 February stating that a customer just informed him/her that representative A had stated that practitioners needed to be CQC registered to administer the product and referred to the previous email stating 'but we received an email on 19 Feb stating that they did not need to be- please can you kindly confirm'. Novo Nordisk submitted that it was unable to find any response from representative A but submitted that he/she might have answered the question verbally via telephone or face-to-face. According to Novo Nordisk, representative A was adamant during the investigation that he/she did not suggest to anyone that Saxenda could be administered by a clinic that was not CQC registered. The Panel noted that whilst the named individual appeared to be confused between not having to be CQC registered to book on the training course and the requirement to be CQC registered to administer Saxenda, it did not consider that there was evidence to show that representative A had provided misleading information that was not capable of substantiation in this regard as alleged. The Panel therefore ruled no breach of Clauses 7.2, 7.4, 9.1 and 2 in this regard.

The complainant further queried what oversight Novo Nordisk had of its representatives carrying out these meetings. According to the complainant, Novo Nordisk had sponsored the pharmacy with 'very significant' funding and then appeared to be delivering the course and preparing the material. The Panel noted Novo Nordisk's submission that it had agreed to sponsor six obesity training meetings throughout 2019. The Panel noted Novo Nordisk's submission that these training events were organised by the named pharmacy, which was in full control of the arrangements; the pharmacy invited relevant health professionals and managed the attendees; it also prepared the agenda, organised all the sessions, any external speakers and provided any relevant materials to the attendees. Novo Nordisk provided a copy of its Meetings SOP, UK which covered the procedure for sponsored meetings. The Panel noted Novo Nordisk's submission that the training meetings had been agreed as part of the head office planning process and the SOP was followed. The Panel noted that Novo Nordisk classified the meeting as a third party meeting that it had sponsored and, in that regard, it appeared that the meetings SOP provided might not have prevented the acts/omissions of the two representatives. The Panel did not have the meeting approval form or sponsorship agreement before it but noted that the 'meetings sponsored' section of the SOP itself did not refer to the role of representatives

and/or certification of material or cross-refer to other relevant SOPs in this regard. The SOP detailed the approval requirements for the arrangements of meetings sponsored by Novo Nordisk. The Panel noted its comments and rulings above including its ruling of a breach of Clause 15.2. The Panel did not consider that the complainant had provided evidence that Novo Nordisk had failed to maintain high standards in relation to its oversight of the sponsorship of the training meetings. No breach of Clause 9.1 was ruled.

The Panel noted that Clause 15.9 had been raised but did not consider that there was an allegation in this regard and therefore made no ruling.

Whilst the Panel was concerned about the activities of the representatives, noting its comments and rulings above, it did not consider that, overall, the circumstances warranted a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's material and activities. No breach of Clause 2 was ruled.

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During the consideration of this case, the Panel was concerned to note that, whilst the first slide of the presentation titled 'Obesity: causes, consequences and treatment' stated 'This sponsored symposium is funded by Novo Nordisk', the Saxenda training agenda provided by Novo Nordisk only contained the Novo Nordisk logo on the top left-hand corner but did not state exactly what Novo Nordisk's involvement was contrary to the meetings SOP. The Panel further queried whether the meeting could be considered a third-party meeting sponsored by Novo Nordisk when the majority of the meeting was about Novo Nordisk's medicine and the majority of presentation time on the agenda was for Novo Nordisk employees.

The Panel noted Novo Nordisk's submission that the materials were not to the standard it would require had they been Novo Nordisk materials. The Panel noted that despite asking Novo Nordisk twice to comment on the allegation that the documents provided by the complainant were inaccurate and contained information which differed from the SPC, Novo Nordisk provided no comments. Nor did Novo Nordisk provide a copy of the SPC as requested.

The Panel asked that Novo Nordisk be advised of its concerns.

Complaint received **7 May 2019**

Case completed **19 December 2019**