CASE AUTH/3115/11/18

ANONYMOUS NON-CONTACTABLE v NOVO NORDISK

Advisory boards

An anonymous, non-contactable complainant who described him/herself as a concerned health professional submitted a complaint about Novo Nordisk advisory boards.

The complainant stated that in the current climate of companies using advisory boards as disguised promotion he/she wished to bring to the Authority's attention that Novo Nordisk had been working in breach of the ABPI Code by hosting multiple advisory boards with the same customers on a repeated basis over the last 5 years. The complainant alleged that the transfer of value of some of the health professionals attending such advisory boards was excessive and not a legitimate activity to gain insights but to reward.

The complainant referred to advisory boards hosted at a named embassy and in the presence and company of the ambassador. Often the advisory boards were vehicles for senior leaders to 'sell' strategic plans rather than elicit insights; these presentations lasted longer than was deemed an acceptable time limit. These strategic advisory boards were held every year and exactly the same key opinion leaders attended. The company also held product advisory boards and, in some years, had held them locally with the same thought leaders and between 2012 and 2018 over 250 advisory boards had been conducted. The complainant was bemused about what information Novo Nordisk was legitimately seeking for these numbers of advisory boards.

The detailed response from Novo Nordisk is given below.

The Panel was concerned at the number of advisory board meetings at around 200 in 6 years. Novo Nordisk needed to be very certain that each met the requirements of the Code, particularly the legitimate need for the services and the criteria for and number of consultants. The Panel was unsure whether there was always a justifiable need for similar advisory boards in different areas of the UK. However, the complainant had only provided limited information and no detailed allegations had been made in this regard.

The Panel was also concerned that there was a lack of pre-reading for some of the advisory boards, for example three of the four advisory boards held at the named embassy. The minutes/reports etc provided for some of the advisory boards showed some of the learnings gained. It was not always clear from the documentation that the focus was on obtaining feedback. For some meetings the proportion of time on the agenda allocated to presentations did not appear to allow adequate time for discussion. Feedback from the participants should be the main focus of these meetings and only a small proportion of the time should be spent on company presentations. There were additional concerns about the advisory boards at the named embassy including the justification for the presence of the ambassador, the length of presentations compared to the time seeking advice (for example one meeting at the embassy the time allocated for presentations was just under two hours (not including the opening and concluding presentations) compared with just over two hours for feedback), the number of advisors and the ratio of Novo Nordisk staff to advisors at some meetings, and that dinner was provided despite the meetings starting at 11 or 12 including lunch and finishing between 5 and 6pm. The Panel queried whether it was usual for very senior Novo Nordisk staff to attend such an advisory board. Given all these concerns the Panel considered that Novo Nordisk had failed to maintain high standards in relation to the advisory boards in general and a breach was ruled.

The Panel noted that the complainant had provided no evidence with regard to the payments for attending advisory boards or that there was not a legitimate need for them. Although the Panel had concerns it did not consider that the complainant had shown on the balance of probabilities that the arrangements were unacceptable as alleged. The Panel ruled no breaches of the Code. This ruling applied to the range of meetings since 2012.

Although the Panel had concerns it did not consider the complainant had shown on the balance of probabilities that the advisory boards were disguised promotion and no breach of the Code was ruled. This ruling applied to the range of meetings since 2012.

The Panel noted its concerns about some of the hospitality provided. Again the complainant was not clear about his/her concerns and had provided no evidence. Given the generality of the allegations, the Panel's view was that the complainant had not satisfied the burden of proof. The Panel therefore ruled no breach of the Code. This ruling applied to the range of meetings since 2012.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure.

An anonymous, non-contactable complainant who described him/herself as a concerned health professional submitted a complaint about Novo Nordisk advisory boards.

COMPLAINT

The complainant stated that in the current climate of companies using advisory boards as disguised promotion he/she wished to bring to the Authority's

attention that Novo Nordisk had been working in breach of the ABPI Code by hosting multiple advisory boards with the same customers on a repeated basis over the last 5 years. The complainant alleged that when assessing the transfer of value of some of the health professionals attending such advisory boards, it was excessive and not a legitimate activity to gain insights but to reward.

The complainant referred to advisory boards hosted at a named embassy and in the presence and company of the ambassador. Often the advisory boards were vehicles for senior leaders to 'sell' strategic plans rather than elicit insights; these presentations lasted longer than was deemed an acceptable time limit. These strategic advisory boards were held every year and exactly the same key opinion leaders attended. The company also held product advisory boards and, in some years, had held them locally with the same thought leaders and between 2012 and 2018 over 250 advisory boards had been conducted. The complainant was bemused about what information Novo Nordisk was legitimately seeking for these numbers of advisory boards.

The complainant alleged breaches of the following and advised the PMCPA to investigate further.

Clause 2	Bringing discredit to the industry
Clause 9	High standards and suitability
Clause 12	Disguised promotion
Clause 18	Inducements and appropriate payments of officials
Clause 22	Meetings, hospitality and sponsorship
Clause 23	Use of consultants – legitimate service.

In writing to Novo Nordisk the Authority referred to Clauses 23.1, 18.1, 12.1, 9.1 and 2. The company was also advised that with regard to Clause 23.1 in the 2016 Code this clause had a different number in the 2011-2014 Codes. The date of the event was relevant.

RESPONSE

Novo Nordisk submitted that given the complainant stated that he/she had an in-depth knowledge of advisory boards which had been held by Novo Nordisk over a long period of time; in its view, and in light of attendees at its advisory board meetings (as detailed further below), such knowledge would be more akin to that of a senior level employee rather than an external health professional advisor. However, Novo Nordisk stated that it took the complaint very seriously and also its responsibilities with regard to holding advisory boards. Despite the broad ranging nature of the allegations, Novo Nordisk had done its best in the short time available to investigate and respond to the matters raised.

Advisory board procedures and policies

Novo Nordisk submitted it had robust processes and policies in place governing advisory boards and referred to its standard operating procedures (SOP) for services such as providing advice at an advisory board.

A specific Novo Nordisk Guidance Document created during 2016 which covered advisory board set up and planning ensured that advisory board meetings were conducted in compliance with PMCPA guidance with clear objectives, focussed questions and sufficient discussion time in order to allow for feedback from advisors. This guidance document also gave direction on inviting relevant advisors and clarified who could be invited based on feedback sought and how often. Furthermore, clear instructions were given regarding venues and locations of advisory boards as well as other factors such as how many advisors could be invited to a meeting and the relevant internal Novo Nordisk attendees who could be involved in such meetings.

Novo Nordisk consistently reviewed its need for advice and consultation reviewing the set-up, conduct and feedback from advisory boards multiple times a year. As part of this review it had evaluated who it had sought advice from as well as how it implemented that advice across the company through follow-up action plans.

Background to Novo Nordisk therapeutic areas

Novo Nordisk submitted that the main therapeutic areas for Novo Nordisk currently were diabetes and cardiometabolic disease, obesity, haemophilia, growth hormone therapy and women's health. Additionally, Novo Nordisk was also developing into newer therapeutic areas (brief details were provided) which impacted its activities and led to a significant need for further advice.

Diabetes had been and remained the mainstay of Novo Nordisk's therapeutic focus. Diabetes was very prevalent, affecting 6% of the UK population and costing the NHS approximately 10 billion pounds per year in direct costs with an equal amount in indirect costs. Furthermore, diabetes was linked with lifestyle choices and was, therefore, a disease which required constant and significant discussion and collaboration with health professionals to understand the social and medical implications of treatments. Within diabetes there were significant differences in treatment of patients with type 1 diabetes and type 2 diabetes. Within the NHS, diabetes care occurred across primary, intermediate and secondary care with multiple therapies and care pathways involving many specialities. Given the primary care focus on diabetes, there were substantial local and regional variations in care and types of therapies commissioned across different clinical commissioning groups (CCGs) and formularies around the country.

Overview of advisory boards November 2012 – November 2018

Novo Nordisk provided a summary document of the advisory boards held in the past 6 years, showing number held per year and related area of advice.

In the period November 2012 – November 2018 (inclusive) Novo Nordisk held 202 advisory board meetings to gain advice at national, regional or local levels across the various therapeutic areas. The

objectives had varied across the years from input to clinical trials, clinical care, NHS structure, patient pathways, to patient experience and funding.

UK healthcare evolution and Novo Nordisk's evolving focus had been the underlying driver for seeking external advice. During this timeframe Novo Nordisk launched 7 new medicines across its existing therapy areas (diabetes, obesity and haemophilia), expanded focus to cardiovascular disease as a result of an updated label for GLP1-RA therapies in patients with diabetes and cardiovascular disease, and changed its prices and pricing strategy post-launch for its basal insulin, Tresiba. Novo Nordisk had also updated its pipeline and therapeutic focus substantially and changed its strategy in its Women's Health franchise. (brief details were provided). Additionally, there had been a large volume of new data for which Novo Nordisk had sought advice on relevance and impact on UK practice and commissioning.

In addition, changes in NHS structure and devolved functioning such as the introduction of CCGs, sustainable and transformation partnership (STPs) and regional medicines optimisation committees (RMOCs) had had fundamental effects on medicine commissioning in primary and secondary care. With the primary care focus for diabetes, this led to significant heterogeneity of care across the UK and localization of medicine procurement across over 200 CCGs in 2013/2014. This, in turn, led to a change in therapeutic treatment across the country with significant localization of care leading to a differing availability of therapies across postcodes around the country which gave rise to a need for more localised advice. Further changes to NHS structure with the creation of STPs (with a clear mandate on diabetes) and RMOCs occurred in 2016. Given the nature of these changes and their effects on local commissioning, Novo Nordisk had sought advice from health professionals and other relevant decision makers working in the local areas on these changes during that time period.

Novo Nordisk provided a detailed overview of the advisory boards, including the dates they were held, location, number of advisors attending and objectives to give further granularity on the points raised above.

In line with PMCPA guidance, Novo Nordisk submitted it had continuously reviewed the nature and set up of its advisory boards and the feedback provided by each advisory board across the years. This had led to changes in the number, structure, function and attendees of its advisory boards over the years. For example, as the NHS commissioning structure had changed and commissioning had become more focussed across APCs (area prescribing committees) and larger formularies, Novo Nordisk had ceased to seek advice on local commissioning changes.

Venues

Novo Nordisk provided locations of various advisory boards and submitted that its SOP gave clear direction about suitable venues for meetings, and was in line with Clause 22.1.

In the last 6 years, Novo Nordisk had held 4 advisory board meetings at the meeting space at the embassy. These meetings occurred between December 2012 and November 2015. Novo Nordisk submitted that the costs for the meetings, including sustenance, were within the range of other local hotel venues and within ABPI limits. The embassy and meeting room were certainly not lavish. Any sustenance provided had been functional and not excessive. Novo Nordisk understood that over the years, the embassy meeting space had been used for multiple business and health related events; nevertheless, given the potential perception, Novo Nordisk elected in 2015 to stop using the embassy for advisory board purposes.

All other advisory board meetings had been held at hotels, conference centres, colleges and the Novo Nordisk offices.

Advisors attending multiple advisory board meetings

Novo Nordisk stated that the selection of advisors had been based on expertise, knowledge and ability to contribute on issues relevant to the objectives of the meeting. This had inevitably led to some overlaps between years.

In the timeframe, a number of advisors had attended more than one advisory board. This was because they were leading experts in their field, and were the right person to provide advice to fulfil the clear objective of the advisory board. Advisors who had attended multiple advisory boards were selected for their knowledge, research interests, participation in multiple clinical trials and expertise at national and regional levels. Some of these advisors also had key roles in multiple NHS and access committees at a national, regional or local level.

Documentation regarding meetings and advisor honoraria

Novo Nordisk carefully considered the PMCPA request for relevant materials such as meetings invitations, agenda and minutes and had strived to provide as full a picture as possible consistent with its other obligations of data privacy and resources and time available. Due to the volume of paperwork and respecting the timeframe, Novo Nordisk took an approach of providing all supporting documents for the past 2 years (2017-2018). This included invitations, agendas, minutes and follow-up documents. It provided a template invitation as an example of what was sent to advisors for these meetings; in those instances where a different template was used, that had been provided. Remaining documents (2012-2016) could also be available upon further request. All other requested details were provided for the full period.

Novo Nordisk stated it adhered to the data minimisation principle in accordance with General Data Protection Regulation (GDPR) requirements, and had, therefore, provided de-identified data in relation to remuneration, where it had redacted the names of the health professionals. Each advisor was assigned a numerical identifier and their payments

set out; thus, it was possible to see how many advisors attended multiple advisory boards over the 7 year period and fees for service paid.

Fair market value documents 2015 and 2018 outlining Novo Nordisk rates were provided. The payments had been disclosed.

Novo Nordisk submitted that the allegations were unfounded and it had not breached Clauses 23.1, 18.1, 12.1, 9.1 and 2 of the 2016 Code.

In response to a request for further information Novo Nordisk confirmed that the 'Ad board honoraria' tab provided data on the numbers of times each healthcare professional attended Novo Nordisk advisory boards during the period 2012 – 2018 (November to November). Unfortunately there was an error in the original spreadsheet; during the process of de-identifying the data, some meetings with common titles but in fact separate events were mistakenly given the same meeting number. Therefore it looked like a small number of healthcare professionals had attended the same meeting more than once. An updated spreadsheet was provided.

Attendance at multiple advisory boards

With regard to attendance at multiple advisory boards, Novo Nordisk submitted that some healthcare professionals had attended more than one advisory board in a year. There were several reasons why this might occur. Each advisory board had a different focus and advice required, which was reflected in the objectives for the advisory board. However, there might be a limited number of specialists who were able to give advice about a particular topic. For example, if advice was required for market access and reimbursement for diabetes therapies in Wales, there might be one or two healthcare professionals who had the knowledge to give advice on this. The same healthcare professional might also be a clinical trial investigator who would then be part of a limited number of professionals who were able to give advice on a more scientific level at a different advisory board.

In addition, some therapy areas had a very limited number of specialists at this time (eg obesity). As obesity was a risk factor for type 2 diabetes, some diabetes specialists were also obesity specialists and therefore might be invited to advisory boards in both therapy areas. As stated in its initial response, some advisors also had key roles in multiple NHS and access committees at a national, regional or local level.

Novo Nordisk submitted that it applied robust selection criteria to identify those who were invited to attend advisory boards. Expertise in the subject matter of interest drove the identification process. Aligned with the industry practice, identification of experts was carried out through an external third party mapping, using desktop research and peer nomination. This approach enabled an objective identification process that was repeated every three years to ensure the most updated list of experts were available based on emerging research and practices.

Fair Market Value rates

In response to the question from the Panel about the differences in fair market value rates paid to certain individuals in earlier years compared to later years; two health professionals were highlighted, Novo Nordisk submitted that sometimes advisors were paid less than the maximum fair market value amount. This accounted for lower payments.

Novo Nordisk submitted that one of the health professionals attended an advisory board in 2013 and chaired the meeting; there was one hour preparation time in addition to the advisory board time (1+2 hours). The hourly rate was in line with the Fair Market Value rates in 2013. Whilst looking at the details of advisory board attendance and work for this health professional, Novo Nordisk discovered that he/she had also attended two other advisory boards in 2013. The company updated the spreadsheet to accurately reflect these details.

The other health professional was the chair of the advisory board meeting in 2013, and as such had to undertake preparation work. This was in addition to the 6 hours service at the advisory board meeting. Unfortunately, Novo Nordisk stated that it did not have the corresponding paperwork to show the preparation work – it was approximately five and a half years ago and it was thought that a Novo Nordisk employee might have deleted some information given he/she thought it would no longer ever be needed. Novo Nordisk would expect 1 or 2 hours preparation for this advisory board. Details of the hourly rate were provided based on a 2 hour preparation.

Advisory boards held at the embassy

Novo Nordisk provided the supporting documentation for the four meetings held at the embassy listing the advisors, their honoraria, and the fair market value rate per hour. Information regarding the subsistence for attendees and additional cost information was also provided.

In response to a further request for additional information Novo Nordisk provided copies of the minutes for the four meetings at the named embassy. There was no pre-reading for three of these meetings (2012, 2013 and 2015) and for the other (2014) the pre-reading consisted of a clinical paper (Buse *et al*, 2014) and summary of product characteristics (SPC) for Xultophy. Novo Nordisk provided a document detailing how the advice had been used. Three of the advisory boards were to gain advice on the Novo Nordisk portfolio and pipeline at a strategic level, discussing Phase 2 data in some cases. Novo Nordisk stated that the advice gained had led to changes in strategy and planning for the therapy areas in question.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but that, like all other complaints, the complainant had the burden

of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations and could not be contacted for more information. The PMCPA was not an investigatory body as such.

The Panel noted that it was acceptable for companies to pay health professionals and others for relevant advice. Nonetheless, the arrangements for such meetings had to comply with the Code, particularly Clause 23. To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. Invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

The Panel noted that Clause 22.1 stated that hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting, ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. Clause 22.1 applied to scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The supplementary information to Clause 22.1 also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'Would you and your company be willing to have these arrangements generally known?'. The impression that was created by the arrangements for any meeting must always be kept in mind.

The Panel was concerned at the number of advisory board meetings at around 200 in 6 years. Companies needed to be very certain that each met the requirements of the Code, particularly the legitimate need for the services and the criteria for and number of consultants. The Panel was unsure whether there was always a justifiable need for similar advisory boards in different areas of the UK. However, the complainant had only provided limited information and no detailed allegations had been made in this regard.

The Panel was also concerned that there was a lack of pre-reading for some of the advisory boards, for example three of the four advisory boards held at the named embassy. The minutes/reports etc provided for some of the advisory boards showed some of the learnings gained. It was not always clear from the documentation that the focus was on obtaining feedback. For some meetings the proportion of time on the agenda allocated to presentations did not appear to allow adequate time for discussion. Feedback from the participants should be the main focus of these meetings and only a small proportion of the time should be spent on company presentations. There were additional concerns about the advisory boards at the named embassy including the justification for the presence of the ambassador, the length of presentations compared to the time seeking advice (for example one meeting at the embassy the time allocated for presentations was just under two hours (not including the opening and concluding presentations) compared with just over two hours for feedback), the number of advisors and the ratio of Novo Nordisk staff to advisors at some meetings, and that dinner was provided despite the meetings starting at 11 or 12 including lunch and finishing between 5 and 6pm. The Panel queried whether it was usual for very senior Novo Nordisk staff to attend such an advisory board. Given all these concerns the Panel considered that Novo Nordisk had failed to maintain high standards in relation to the advisory boards in general and a breach of Clause 9.1 was ruled. (This clause was the same in codes since 2008).

The Panel noted that the complainant had provided no evidence with regard to the payments for attending advisory boards or that there was not a legitimate need for them. Although the Panel had concerns it did not consider that the complainant had shown on the balance of probabilities that the arrangements were unacceptable as alleged. The Panel ruled no breach of Clause 23.1 and consequently no breach of Clause 18.1. This ruling applied to the range of meetings since 2012, when the relevant clauses were 20.1 and 18.1 until the 2016 Code when the relevant clauses were 23.1 and 18.1)

Although the Panel had concerns it did not consider the complainant had shown on the balance of probabilities that the advisory boards were disguised promotion and no breach of Clause 12.1 was ruled. This ruling applied to the range of meetings since 2012. (This clause was the same in codes since 2008).

The Panel noted its concerns about some of the hospitality provided. Again the complainant was not clear about his/her concerns and had provided no evidence. Given the generality of the allegations, the Panel's view was that the complainant had not satisfied the burden of proof in relation to Clause 22. The Panel therefore ruled no breach of Clause 22.1. (This ruling applied to the range of meetings since 2012 when the relevant clause was 19.1 until the 2016 Code when the relevant clause was 22.1).

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure.

Complaint received **7 November 2018**

Case completed **1 April 2019**