NO BREACH OF THE CODE

CASE AUTH/3261/10/19

COMPLAINANT V NOVO NORDISK

Alleged conduct of medical employees

A contactable individual complained about the conduct of regional medical advisors from Novo Nordisk. The complainant stated that the regional medical advisors were supposed to be reactive to clinicians but at Novo Nordisk they proactively asked representatives to take them into meetings even though they had not been invited. The complainant alleged that meetings conducted and booked by the representatives were normally held by the medical advisor and the representatives were also present. The medical advisor seemed to be doing more of the selling which the complainant stated was in absolute violation of any medical staff he/she had ever worked with. The complainant alleged that the medical advisors were given call rates by senior managers. They were under pressure to see a certain number of customers a day and had meeting targets. This made them pressure the representatives to get them to attend meetings with them. There was no clear line whether the meetings were reactive medical or promotional and proactive.

The complainant submitted that most people felt very uncomfortable with what the medical advisors were doing but senior management took no notice. The complainant stated that never in his/her career in the pharmaceutical industry had there been so much promotional activity by medical advisors and such pressure by them on the representatives to take them into every meeting whether the customer had requested their presence or not.

The detailed response from Novo Nordisk is given below.

The Panel noted that 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 made detailed allegations but provided little evidence in support.

The Panel noted that the Code defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. A representative was defined as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call representatives.

The Panel disagreed with Novo Nordisk's submission that the regional medical advisor team was non-promotional and was not provided with any promotional materials to use with health professionals.

The Panel noted that given the regional medical advisor's role and the broad definition of promotion in the Code there was a possibility that their interactions with health professionals etc, especially those initiated by the company, might be considered promotional. The Panel noted that the status of each such interaction should be considered on its individual merits.

The Panel noted that the briefing document for the regional medical advisors stated that RMAs have a predominantly non-promotional role. It stated that on-licence/label discussions could occur with both diabetes care specialists (sales representatives) (DCS)/diabetes outcome directors (DOD) and regional medical advisors present. The briefing further stated that a regional medical advisor could present proactive, on-licence data at a DCS arranged meeting and that this would be a promotional activity. The example of the pre-approved presentation used by the regional medical advisors provided was a presentation on the management of hyperglycaemia in type 2 diabetes . Slides included the indications for Victoza (liraglutide), Tresiba (insulin degludec), Levemir (insulin detemir) and Ozempic (semaglutide) as well as prescribing information.

In the Panel's view part of Novo Nordisk regional medical advisor's role was promotional. The Panel noted that whilst this was not necessarily unacceptable, provided it was done within the requirements of the Code, companies would need to be extremely careful to ensure that such promotional activity was very clearly separated from the non-promotional role of a medical and scientific liaison executive and the like and that the distinction must be clear to health professionals. The Code did not prohibit MSLs and the like from promoting medicines as such.

The Panel noted Novo Nordisk's submission that there were times where a regional medical advisor might visit a health professional with a representative; such occasions were not routine and a legitimate need was required for the joint visit to take place.

The Panel further noted Novo Nordisk's submission that meetings might be arranged by a representative where the regional medical advisor would present on licence data and use pre-certified slides but it was always made clear at these meetings that such presentations were being made by a regional medical advisor. The Panel did not consider such proactive presentations by Novo Nordisk staff could be anything other than promotional.

The Panel noted that the complainant bore the burden of proof and had not established that any of these meetings constituted disguised promotion. No breach of the Code was ruled.

The Panel noted that representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code. The Panel noted that on the evidence before it the complainant had not established, on the balance of probabilities, that a regional medical advisor had pressurised representatives to book and take them to most meetings or had acted in a manner which was contrary to this requirement and based on the narrow allegation, the Panel ruled no breach of the Code.

The Panel noted Novo Nordisk's initial submission that it was categorically untrue that regional medical advisors were given call rates by senior management or were under pressure to see a certain number of customers a day. The regional medical advisor team was not set call or contact rate targets.

The Panel noted Novo Nordisk's submission that the regional medical advisors were expected to have regular non-promotional interactions with health professionals which might include responding to enquiries. Part of the role was also to act as an expert speaker, similar to an external key opinion leader, at meetings with groups of health professionals (details were provided of the number of meetings per month on average). According to Novo Nordisk this was a suggested activity level and was not a target on which performance was based and was not linked to remuneration or bonus.

The Panel further noted Novo Nordisk's subsequent submission in response to a request for further information that there was a suggested minimum activity level of interactions with health professional per month (details provided). According to Novo Nordisk this was not a target on which performance was based and was not linked to remuneration or bonus and such an interaction was likely to occur following a request by a health professional to respond to a specific enquiry, to gauge interest in clinical trial participation or as a result of a presentation given.

The Panel accepted that there was a difference between a target for performance on which a bonus was paid and a suggested minimum activity. Employees would be motivated to meet their suggested activity levels.

The Panel noted that the complainant bore the burden of proof and had not established that the suggested minimum activity levels as described by Novo Nordisk were such that they were in breach of the requirements of the Code.

The Panel noted its comments and rulings above and on balance did not consider that there was evidence to show that based on the specific allegations Novo Nordisk had failed to maintain high standards. The Panel therefore ruled no breach of the Code including Clause 2.

A contactable individual complained about the conduct of regional medical advisors from Novo Nordisk Ltd.

COMPLAINT

The complainant noted that the regional medical advisors were supposed to be reactive to clinicians but at Novo Nordisk they proactively asked representatives to take them into meetings even though they had not been invited. They proactively asked the representatives to book meetings by emailing them with their available dates and pressurised them to take them to most meetings. Meetings conducted and booked by the representatives were normally held by the medical advisor and the representatives were also present. The medical advisor seemed to be doing more of the selling which the complainant stated was in absolute violation of any medical staff he/she had ever worked with. The complainant alleged that the medical advisors were given call rates by senior managers so they were under pressure to see a certain number of customers a day and they had meeting targets too. This made them pressure the representatives to get them to attend meetings with them. There was no clear line whether the

meetings were reactive medical or promotional and proactive. The complainant submitted that most people felt very uncomfortable with what the medical advisors were doing but senior management took no notice. The complainant stated that never in his/her career in the pharmaceutical industry had there been so much promotional activity by medical advisors and such pressure by them on the representatives to take them into every meeting whether the customer had requested their presence or not.

The complainant stated that he/she was sure that medical advisors were not supposed to proactively ask for appointments without customer consent and they certainly could not just do a lunch meeting that had been given to the representative to do and the medical advisor had not been invited. The complainant stated that it was shocking that the metrics were based on pushing for proactive meetings without consent from the clinicians.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1 and 15.2 of the Code.

RESPONSE

Novo Nordisk noted that the complainant had provided little information and no documentation to support his/her complaint.

Novo Nordisk explained that the regional medical advisors were a team of field-based medical staff. The team reported through the regional medical affairs manager to the head of medical affairs & education who in turn reported to the clinical, medical and regulatory director.

Novo Nordisk submitted that the regional medical advisors were non-promotional and they were not remunerated based on sales of medicines in their region. The team's key accountability was to exchange credible scientific and medical information with health professionals and to ensure that health professionals were aware of and could understand the scientific basis for, and clinical usefulness of, Novo Nordisk products. The team worked cross functionally in a non-promotional capacity with representatives and market access colleagues.

The team of regional medical advisors received regular verbal briefings (during initial onboarding and ongoing training events and on accompanied field visits with their manager), which were supported by a briefing document on their required behaviours (copy provided). This included how they were expected to interact with representatives and market access colleagues.

Novo Nordisk stated that its training programme for the regional medical advisors was robust. On commencing the role, an individual was assigned a more experienced regional medical advisor 'buddy', along with 1:1 training with his/her manager. Regional medical advisors were hired with a probationary period during which their activities were undertaken together with either their 'buddy', manager or other experienced team member. At the end of the probationary period, individuals were tested on their clinical knowledge as well as their knowledge of how to conduct activities, before being signed off as permanent employees. Regional medical advisors were also assigned appropriate training via a validated online training portal.

Novo Nordisk submitted that it was categorically untrue that regional medical advisors were given call rates by senior management or were under pressure to see a certain number of customers a day. The team was not set call rate targets.

There were times where a regional medical advisor might visit a health professional with a representative. Such occasions were not routine and a legitimate need was required for the joint visit to take place, for example, the health professional had requested to be introduced to the regional medical advisor or the regional medical advisor had been requested to attend in order to respond to technical on-label questions raised previously by the health professional. In this example the request would be captured by the representative and relayed to the regional medical advisor.

Novo Nordisk submitted that the regional medical advisors were expected to have regular non-promotional interactions with health professionals which might include responding to enquiries. Part of the role was also to act as an expert speaker, similar to an external key opinion leader, at meetings with groups of health professionals (a number (provided) of meetings per month on average). The meetings might be arranged by a representative. In such situations, the regional medical advisor would only present on licence data and use pre-certified slides. It was always made clear at these meetings that such presentations were being made by a regional medical advisor.

Regional medical advisors were not provided with any promotional materials to use with health professionals, but they could access clinical papers, posters, abstracts and pre-approved presentations (an example presentation was provided).

Based on the above information, Novo Nordisk stated that it was clear that the requirements of Clauses 15.2, 12.1, 9.1 and 2 of the Code had been fulfilled.

In response to a request for further information, Novo Nordisk stated that the regional medical advisor team was not set call or contact rate targets. There was a suggested minimum activity level of interactions with health professionals per month (number provided), however this was not a target on which performance was based and was not linked to remuneration or bonus. Such an interaction was likely to occur following a request by a health professional to respond to a specific enquiry, to gauge interest in clinical trial participation or as a result of a presentation given. In addition, as mentioned, the regional medical advisors also acted as expert speakers (similar to an external key opinion leader) at meetings with groups of health professionals (number of meetings per month on average provided). This was a suggested activity level and was not a target on which performance was based and was not linked to remuneration or bonus.

The regional medical advisors recorded their interaction with health professionals in a customer relationship management (CRM) system. A summary of the interactions recorded between September 2018 and September 2019 was provided. This summary also included information not recorded in the CRM system. Novo Nordisk submitted that this information was confidential.

Novo Nordisk submitted that regional medical advisors were not representatives as defined by the Code and therefore were not required to take the ABPI medical representative examination.

The first two key/main accountabilities in the regional medical advisor job description were assessed qualitatively based on observed feedback from the regional medical advisor's

manager or other medical colleagues, unsolicited health professional feedback and feedback from other Novo Nordisk staff if they had been present. There were no metrics for these accountabilities. The regional medical advisor's objective was to communicate scientific data to the expert community, increase health professionals' and trialists' medical knowledge and to further support Novo Nordisk's overall goals by acting as internal scientific experts within teams, answering queries and educating colleagues.

The briefing document for the regional medical advisors was sent to them by email as well as to commercial colleagues, namely the diabetes care specialists (sales representatives) and diabetes outcome directors. It was not formally approved. It was trained out at local team meetings.

The activities of the regional medical advisor team and how it was expected to interact with health professionals and other relevant decision makers were not set out in a specific standard operating procedure (SOP). However, regional medical advisors were assigned SOPs relating to Code requirements, including SOPs on Meetings, Engaging Health Professionals, Other Relevant Decision Makers, Patients and Journalists for Services to Novo Nordisk and Novo Nordisk Business Ethics requirements.

The example presentation provided was used in a setting where the regional medical advisor had acted as an expert speaker on behalf of Novo Nordisk, most likely at a meeting arranged by a Novo Nordisk sales representative. A similar version of the presentation was available for use in response to unsolicited requests for information from health professionals. The regional medical advisors did not act in a promotional capacity. Their role was non-promotional and was clearly understood as such throughout the business.

PANEL RULING

The Panel noted that 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 made detailed allegations but provided little evidence in support.

The Panel noted that Clause 1.2 of the Code defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that Clause 1.7 defined a representative as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call representatives.

The Panel disagreed with Novo Nordisk's submission that the regional medical advisor team was non-promotional and was not provided with any promotional materials to use with health professionals.

The Panel noted that according to the regional medical advisor's job description the main outcome of the role was to ensure local health professionals were aware of and understood the scientific basis for and clinical usefulness of the company's compounds. The job description included references to supporting new business opportunities and the need to take into account local and national business needs. The job description listed key/main accountabilities:

including providing, *inter alia*, education and training across business area functions to the external customers, healthcare professionals, key opinion leaders and Novo Nordisk staff (where appropriate) and facilitating development of symposia/meetings or education seminars for health care providers on subjects relevant to Novo Nordisk products. It also mentioned facilitating publications on Novo Nordisk products, local clinical trials and phase IV studies.

The Panel noted that given the regional medical advisor's role and the broad definition of promotion in the Code there was a possibility that their interactions with health professionals etc, especially those initiated by the company, might be considered promotional. The Panel noted that the status of each such interaction should be considered on its individual merits.

The Panel noted that the briefing document for the regional medical advisors stated that RMAs have a **predominantly** non-promotional role. It stated that on-licence/label discussions could occur with both diabetes care specialists (sales representatives) (DCS)/diabetes outcome directors (DOD) and regional medical advisors present. The briefing further stated that a regional medical advisor could present proactive, on-licence data at a DCS arranged meeting and that this would be a promotional activity. The example of the pre-approved presentation used by the regional medical advisors provided was a presentation on the management of hyperglycaemia in type 2 diabetes. Slides included the indications for Victoza (liraglutide), Tresiba (insulin degludec), Levemir (insulin detemir) and Ozempic (semaglutide) as well as prescribing information.

The Panel noted that PMCPA Guidance about Clause 3 included that if as part of their role, the medical and scientific liaison executives (MSL) and the like promote licensed products and indications then they were covered by the Code including the specific requirements for representatives (Clauses 15 and 16). In the Panel's view part of Novo Nordisk regional medical advisor's role was promotional.

The Panel noted that whilst this was not necessarily unacceptable, provided it was done within the requirements of the Code, companies would need to be extremely careful to ensure that such promotional activity was very clearly separated from the non-promotional role of a medical and scientific liaison executive and the like and that the distinction must be clear to health professionals. The Code did not prohibit MSLs and the like from promoting medicines as such.

The Panel noted Novo Nordisk's submission that there were times where a regional medical advisor might visit a health professional with a representative; such occasions were not routine and a legitimate need was required for the joint visit to take place, for example, the health professional had requested to be introduced to the regional medical advisor or the regional medical advisor had been requested to attend in order to respond to technical on-label questions raised previously by the health professional The Panel noted that Clause 1.2 provided an exemption to the definition of promotion stating that replies made in response to individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, were excluded from the definition of promotion, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. The Panel noted that the exemption only applied to unsolicited enquiries, an enquiry made without any prompting from the company. If an enquirer subsequently requested further information this could be provided and would be exempt from the Code provided the additional information met the requirements of this exemption. The Panel noted that when relying on this

limited exemption in relation to a meeting about an unlicensed product, documentation was very important.

The Panel further noted Novo Nordisk's submission that meetings might be arranged by a representative where the regional medical advisor would present on licence data and use pre-certified slides but it was always made clear at these meetings that such presentations were being made by a regional medical advisor. The Panel did not consider such proactive presentations by Novo Nordisk staff could be anything other than promotional.

The Panel noted that the complainant bore the burden of proof and had not established that any of these meetings constituted disguised promotion. No breach of Clause 12.1 was ruled.

The Panel noted that Clause 15.2 stated that representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code. The Panel noted that on the evidence before it the complainant had not established, on the balance of probabilities, that a regional medical advisor had pressurised representatives to book and take them to most meetings or had acted in a manner which was in breach of Clause 15.2. Based on the narrow allegation, the Panel ruled no breach of Clause 15.2.

The Panel noted Novo Nordisk's initial submission that it was categorically untrue that regional medical advisors were given call rates by senior management or were under pressure to see a certain number of customers a day. The regional medical advisor team was not set call or contact rate targets.

The Panel noted Novo Nordisk's submission that the regional medical advisors were expected to have regular non-promotional interactions with health professionals which might include responding to enquiries. Part of the role was also to act as an expert speaker, similar to an external key opinion leader, at meetings with groups of health professionals (the number of meetings per month on average was provided). According to Novo Nordisk this was a suggested activity level and was not a target on which performance was based and was not linked to remuneration or bonus.

The Panel further noted Novo Nordisk's subsequent submission in response to a request for further information that there was a suggested minimum activity level of interactions with health professional per month. According to Novo Nordisk this was not a target on which performance was based and was not linked to remuneration or bonus. According to Novo Nordisk such an interaction was likely to occur following a request by a health professional to respond to a specific enquiry, to gauge interest in clinical trial participation or as a result of a presentation given.

The Panel noted that PMCPA Guidance about Clause 3 stated that the remuneration of those employed as medical and scientific liaison executives and the like must not be linked to the number of enquiries answered or the number of visits, meetings etc but a bonus scheme linked to the percentage of enquiries or visit requests completed may be acceptable. Remuneration should not be linked to sales in any particular territory or place or to sales of a specific product or products and, in particular, may not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, for example sales in the UK, may be acceptable.

The Panel accepted that there was a difference between a target for performance on which a bonus was paid and a suggested minimum activity. Employees would be motivated to meet their suggested activity levels.

The Panel noted that the complainant bore the burden of proof and had not established that the suggested minimum activity levels as described by Novo Nordisk were such that they were in breach of the requirements of the Code.

The Panel noted its comments and rulings above and on balance did not consider that there was evidence to show that based on the specific allegations Novo Nordisk had failed to maintain high standards. The Panel therefore ruled no breach of Clause 9.1.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was seen as a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

During its consideration of this case the Panel was concerned to note Novo Nordisk's submission that in its view its regional medical advisors were not representatives as defined by the Code and therefore were not required to take the ABPI medical representative examination. The Panel queried whether all aspects of the regional medical advisors' role were truly non-promotional in nature noting the job description, the content of the briefing document and the broad definition of promotion. The Panel considered that it appeared that the arrangements for the regional medical advisors were such that the aspects of the role were not differentiated in a way that ensured compliance with the Code.

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

Complaint received **12 October 2019**

Case completed **3 April 2020**