

CASE/0363/11/24

COMPLAINANT v SANOFI

Allegations about a Diabetes Awards event

CASE SUMMARY

This case was in relation to an awards presentation event which was part of a diabetes awards programme sponsored by Sanofi. The complainant alleged that Sanofi had leveraged its position as sponsor to bias the awards towards initiatives and individuals aligned to Type 1 diabetes care and prepare for the launch of teplizumab and that the awards presentation event constituted disguised promotional activity.

There was an appeal by Sanofi of the Panel's breach ruling.

The outcome under the 2024 Code was:

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| Breach of Clause 5.1 Panel's breach ruling upheld at appeal | Failing to maintain high standards at all times |
| No Breach of Clause 15.6 | Requirement that promotional materials and activities must not be disguised |

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint about Sanofi was received from an anonymous, non-contactable complainant.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

“To Whom It May Concern, I am writing to formally raise a concern regarding what I believe to be a serious breach of the ABPI Code of Practice by Sanofi, specifically in relation to their conduct during the recent [named] Diabetes Awards held on 31st October 2024.

I am deeply disappointed by what appeared to be a deviation from the event's core purpose of recognising excellence in diabetes care across the UK. Instead, there seemed to be a focus skewed towards initiatives and individuals associated with Type 1 diabetes care, which conveniently also links to Sanofi's drug Teplizumab. As an attendee, I observed that Sanofi may have used [named] Diabetes Awards to align itself

within type 1 to prepare for their launch. During the event, a pattern emerged where most, if not all, awards were presented to individuals, projects, or trusts heavily involved in Type 1 diabetes care. As an attendee, I observed that Sanofi may have used [named] Diabetes Awards to align itself within type 1 to prepare for their launch.

During the event a pattern emerged, where majority of winners were involved in Type 1 diabetes care and/or children/young adults which aligns to where screening is promoted or to where they are positioning their new drug, such as the [named] study at [named] Hospital. This selective focus raises questions about the impartiality of the awards.

Furthermore, projects related to Type 2 diabetes were noticeably absent from recognition, suggesting a deliberate emphasis on Type 1 winners. The public and healthcare professionals were led to believe that these awards were granted solely on the basis of merit. However, the apparent bias towards those involved with Type 1 diabetes presents a misleading picture. In line with their submitted indication and with no current Marketing Authorisation in the UK, there are reasons to believe Sanofi leveraged the awards to align themselves to type 1 care.

In light of these observations, I believe that further investigation may reveal that the [named] Diabetes Awards constituted a promotional activity masked as a non-promotional event. [Named awards in] Diabetes is intended to be an impartial, non-promotional awards event that honours true clinical excellence. I encourage the PMCPA to look into this matter to safeguard the integrity of the industry and to ensure transparency and fairness in future."

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 5.1 and 15.6 of the 2024 Code.

SANOFI'S RESPONSE

The response from Sanofi is reproduced below:

"We refer to your letter dated 18th November 2024, in which you notified Sanofi UK of a complaint received under the Code of Practice for the Pharmaceutical Industry from an anonymous non-contactable complainant who describes him/herself as a healthcare professional.

Sanofi is disappointed that such a complaint has been made, as the company is committed to maintaining high standards in our work and in complying with the Code in all relevant activities.

The complainant raised concerns relating to the conduct of Sanofi during the recent [named] Diabetes Awards. Our understanding of these concerns is as follows:

1. The complainant alleges that Sanofi has 'leveraged' its position as a sponsor of the [named] awards to bias the awards towards initiatives and individuals aligned to type 1 diabetes care.
2. The complainant suggests that the alleged bias in awards links to centres where type 1 screening is 'promoted' and therefore links to teplizumab with an accusation of disguised promotion.

In formulating our response, we addressed the concerns raised by the complainant and specifically the requirements of Clauses 5.1 and 15.6 of the 2024 ABPI Code of Practice to which we have been asked to respond.

Background

Sanofi has established a significant presence in the field of diabetes care over three decades, with a portfolio that includes several marketed products for the management of both type 1 (autoimmune) and type 2 diabetes. This underlines Sanofi's commitment to diabetes research and treatment reflecting a long-standing dedication to improving patient outcomes in this therapeutic area. Sanofi currently markets six products which are licensed for use in type 1 diabetes.

Teplizumab is a pipeline product that is not yet licenced in the UK and has been investigated for use to delay the onset of Stage 3 type 1 diabetes in adults and children with Stage 2 type 1 diabetes. Stage 2 is asymptomatic although the process of beta pancreatic cell destruction has already started at this stage, meaning that progression to symptomatic type 1 diabetes will occur later. Recent advancements mean that stage 2 can now be detected by antibody tests although these are not routinely available outside of research settings.

Peer reviewed articles have stated that reasons for identifying people with presymptomatic T1D, (by screening for antibodies) include: prevention of the serious potentially life threatening condition diabetic ketoacidosis (DKA) and related morbidities and mortality, reducing the need for hospitalisation, time to provide emotional support and education to ensure a smooth transition to treatment when needed, and opportunities for new treatments to prevent or delay progression. However, it is important to note that there is currently no national screening programme in place in the NHS.

Of those people who might be screened and identified as having positive autoantibodies only a proportion (those with 2 positive antibodies and dysglycaemia) could be potentially eligible for treatment with teplizumab (assuming licensing and reimbursement).

- 1. Allegation that Sanofi has 'leveraged' its position as a sponsor of the [named] awards to bias the awards towards initiatives and individuals aligned to type 1 diabetes care.**

[Named awards programme] is a [name of Organiser] initiative. [The Organiser] is a commercial organisation, not a healthcare or patient organisation. [The Organiser] is a leading international multi-channel media group, producing a range of magazines, websites and communications programmes across the healthcare sector. [The Organiser] also run the [named awards] programme, which supports the NHS by identifying and showcasing initiatives that improve patient care and then disseminating them more widely across the health service. First launched in 2011, therapy areas covered by [named awards programme] include diabetes, dermatology, oncology, hepatitis C and anticoagulation. All categories in the awards programmes support one or more of the domains as defined by the current NHS Outcomes Framework. A [named awards programme] award signifies that an initiative has been highlighted by the NHS,

charities, patient organisations and industry as improving patient experience, standards of care and outcomes.

[The Organiser] created the Diabetes [named awards programme] with the input of a range of partners in the NHS, diabetes charities and patient group experts, including the [list of thirteen named organisations].

At its inception [the Organiser] approached multiple pharmaceutical companies for partnership opportunities and Sanofi was the only company to accept this opportunity. The program has been running for 14 years and Sanofi has been the sole partner in these awards since their inception. Sanofi's position as the sole partner was added to our commercial sponsorship contract a few years after the program began. As a partner in the initiative, Sanofi contribute funding, subsistence, office space to host the awards and three judges.

The annual awards evening event is run at Sanofi's head office to contain expense and to provide a professional venue, large enough to accommodate the event. As such, the venue in Reading is neither lavish nor the primary appeal of the event.

Attendees at the event include a contingent of Sanofi staff. A certified Sanofi briefing is given to all Sanofi attendees that explains the nature of the event and explicitly confirms it as non-promotional. The brief also states that all discussions must remain non-promotional in nature. Naturally discussion of product is barred, and to avoid doubt this is explicitly barred even with known healthcare professionals due to possible proximity to members of the public. Also, it states that the event must not be used to create a promotional opportunity for future engagement and that if a guest proactively asks about a Sanofi product or promotional activity the guest must be advised that Sanofi staff are attending in a non-promotional capacity and therefore not able to discuss anything related to Sanofi products. Due care and attention are also taken to ensure that all materials in use / visible at the awards event at the Reading office relate specifically to the event and not Sanofi products.

[Named awards programme] Judging process

The [named awards programme] program runs over the calendar year. At the beginning of the year, a steering committee meet to review award categories from the previous year and agree on award categories for the new year. The steering committee has four members: one Sanofi employee and three senior healthcare professionals. A representative from [the Organiser] is also present to action any recommendations from the group. The role of the steering committee is to review categories within the program for the upcoming year to ensure they remain relevant to the evolving NHS landscape and to assess the criteria which is applied to the judging process for the entries received. For 2024, one new category was added called "name of category". The judging criteria for individual categories has remained consistent across the last few years, but in 2024 judging criteria were amended to include 'impact to patients'.

In total there are 31 judges for the Diabetes [named awards programme] awards. The judges form a multi-disciplinary panel of leading diabetes healthcare professionals, patient representatives, professional organisations and three Sanofi employees.

The judging process is carried out in the same format each year, [The Organiser] allocate judges to one of three panels, and the three Sanofi judges are distributed equally to these three panels. The categories for each group assesses are allocated by [the Organiser] and are based on the number of submissions for each category to ensure no one group reviews substantially more submissions than another. Each judge is required to sign a confidentiality agreement, receives a 'how to judge guide' from [the Organiser] and scoresheets detailing the set headings on which to judge each category.

[The Organiser] guidance for entries states "The initiatives must be well thought through with clear method, objectives, results, sustainability and conclusions that are specifically related to the aim of the initiative. Projects should have a demonstrable impact on clinical practice, showing how innovation can contribute to the optimisation of service delivery, ultimately benefiting people with diabetes. Judges favour projects that demonstrate results having quality and/or efficiency benefits which could be replicated elsewhere, thereby having a greater impact than their initial focus."

Each judge assesses each entry individually and completes scoresheets with scores for each heading and written justification for the score. These are submitted to [the Organiser] in advance of a group judging day where the panel convene to discuss the nominations and scores. For the group judging meeting every judge's scores are visible to all the other judges to ensure transparency. The judging groups are each chaired by a member of the steering group committee (not a Sanofi employee) and a discussion takes place between the judges on the panel to decide on who are the winners of each category in accordance with judging criteria set out by the steering committee. The winners for each category are agreed after discussion by the whole panel. The judges' confidentiality agreement requires them to destroy any paperwork or documents relating to the judging after the judging day. [The Organiser] retain their own judging notes and overall scorecards until the award winners have been announced. Feedback from [the Organiser] is provided to any entrant on request.

The winners are announced at the awards evening which is hosted in Sanofi's UK office. While no financial remuneration was associated with the awards, the winners gain exposure and acknowledgment for their achievements, potentially opening doors to future opportunities and collaborations.

Contribution of three Sanofi judges

The three Sanofi judges who took part in the 2024 [named awards programme] awards included two healthcare professionals and the original employee who led the partnership with [the Organiser] since its inception. All employees have extensive clinical or industry experience in diabetes.

As part of the investigation in response to this complaint, Sanofi reviewed the process of judging set up by [the Organiser], interviewed the three judges and analysed the award categories over the last 4 years.

The Sanofi judge contributed their opinions and discussion as one of ten contributors in each group, and discussion was mediated by a chair. All judges, including the chair, are representatives of the diabetes community with a strong interest in ensuring recognition of high quality activities in their field of medicine. Awards were judged based on

predefined criteria within predefined categories. This structure effectively limits the opportunity of any one judge, including Sanofi employees, to bias discussion toward their own favoured topics. Discussion and justification of opinions happened openly within the panel.

Where a conflict of interest is present judges can recuse themselves from the discussions, as occurred in a previous year when a project sponsored by Sanofi was being judged. Submissions for the awards are in general focussed on patient care and treatment pathways rather than specific medicines. No specific Sanofi medicines were mentioned in the submissions and no related conflict of interest existed for a nomination for the Sanofi judges for the 2024 nominations.

All three Sanofi judges interviewed stated that they did not influence choice of category or winner beyond their expected contribution to judge according to the predefined criteria for each category.

Award categories

In analysis of award categories, Sanofi notes from the [Organiser] website that the award categories for 2024 are identical to 2023 except for the addition of a new category “name of category”, and the reinstatement of the “[name of category]” award which was present in 2020, 2021, 2022 but not 2023. Categories of awards show very little evolution over 5 years.

[Table of awards categories in 2021, 2022, 2023 and 2024]

Award winners

The winners for the new category for 2024 “[named category]” were analysed to determine if there was a link between Sanofi’s portfolio of licenced and unlicenced diabetes medicines. The category was won by the [named hospital] for their work in identifying care gaps in managing diabetes in people with chronic kidney disease. The comments from the judges were “The entry from the [named hospital] had lots of information and was very well researched. The objectives were clear and it had demonstrable clinical outcomes that could be replicated. This blew the judges away and the improvement in care was fantastic.”

Three other projects were highlighted as highly commended, commended and finalist.

- Highly commended for the [named initiative] which judges commented “The [named] project imposes a high floor, so nobody falls though the net. The judges liked the breadth, national impact and fundamental building blocks. It had real life data that seemed to be updated daily.”
- Commended for a dashboard by [named initiative for locality] Diabetes service combining two data sources to address a range of needs of the local diabetes service (including education, support of care staff, monitoring, improvement of HbA1C) with judges commenting “The [named initiative] work was a big project with big implications across a large community. It was a fantastic example of population health outcomes. The judges liked that it covered diversity with good use of the data.”

- Finalist was for a Quality Improvement Initiative in [named hospital] using data and plan-do-study-act cycles to turn around negative findings in the National Paediatric Diabetes Audit's seven key care processes. For this project the judges commented “[Named hospital]’s project had a clear, methodical approach and a solid set of results. The patient outcomes were impressive and was a whole team approach, with not just the leads taking it forward.”

The Sanofi Green award was judged in a separate process, with two Sanofi judges and two external judges. It was awarded for a team, organisation or individual working in healthcare for an initiative which benefits the environment by reducing carbon emissions.

The complainant suggested that ‘most if not all awards were presented to individuals, projects or trusts heavily involved in type 1 diabetes.’ In responding to this allegation Sanofi reviewed the winners of all categories for 2024, summarised below and attached as reference:

[List of award categories and the initiatives which won, were highly commended or commended and finalists]

The winners of the awards spanned the range of topics associated with living with diabetes, including education, support, newer technologies for monitoring glucose and delivering insulin, surgical preparation, dietary management, diabetic foot, diabetic retinopathy and diabetic kidney disease. Many of these issues apply to type 2 diabetes as well as type 1. No direct or indirect reference to Sanofi diabetes medicines, including teplizumab, are made in the winning submissions or judge’s comments. No awards were on projects which directly or indirectly reference teplizumab, nor a teplizumab population (delayed onset of stage 3 diabetes in stage 2), positioning, data or delivery.

Three awards were decided independently of the [named awards programme] process, and with no involvement of Sanofi, but announced at the [named awards programme] awards. These were [names of awards].

[The Organiser] kindly analysed the award submissions and reported that 52% of submissions were related to Type 1 diabetes, 21% to Type II diabetes, 7% Type I and Type II diabetes with the remainder not indicating a particular subset of diabetes care.

On the basis of the robust judging process outlined above and the list of awards presented in 2024, Sanofi strongly refutes any allegation of undue bias or influence over the [named awards programme] awards and therefore denies any breach of the Code including clause 5.1.

2. Alleged bias in awards to centres where type I screening is ‘promoted’ and therefore links to teplizumab with an accusation of disguised promotion.

The complainant expressed concern about the [named awards programme] awards being biased towards centres ‘promoting’ screening for Type 1 diabetes and a perceived link with our unlicensed product teplizumab.

As outlined in our background information, screening and the concept of early detection has been the subject of research and debate in the field of Type 1 diabetes for many years and there are many good reasons to support the concept of screening in this area regardless of the existence of teplizumab.

The complainant drew particular attention to the [named] study as an example of inappropriate proximity to a pre-licence medicine. The [named] studies are sponsored by the [named academic institution] and are conducted independently of Sanofi. They seek to demonstrate the multifactorial need and acceptability for screening for T1DM. The [named] studies are not teplizumab studies. These clinical research studies did not win an award or special mention in any category of the [named awards programme] awards. Sanofi reviewed the attendance list and the principal investigator for [named studies] was not in attendance. [The Organiser] kindly reviewed submissions for 2024 and found that this study was not submitted for an award.

[Named study] is a T1D screening clinical research study currently recruiting in the UK and originally aimed to recruit 20,000 children aged between 3 and 13, other screening clinical studies are currently ongoing in the UK including [second named study]. The published aim of [named study] is: "We aim to deliver the first formal qualitative study to understand acceptability for a national T1D general population screening program for children in the UK. We aim to explore whether parents and children in the UK would want to be part of a program of testing for T1D, how they would want to be informed and participate in such a program, and how any barriers to recruitment and participation can be addressed."

Sanofi is not currently undertaking any research or funding any UK research in this field. As there is no direct link between research into the provision of early detection and screening services and our pipeline product, Sanofi refutes the idea that it has influenced the [named awards programme] awards to undertake disguised promotion of teplizumab. Sanofi therefore strongly denies breaches of clauses 15.6 and 5.1.

Summary

In summary, [named awards programme] awards are a well-respected annual initiative run by [the Organiser] with the enthusiastic support of a broad range of leaders and associations in the clinical and patient diabetes community. The event serves an important role in highlighting innovation and excellence in the provision of diabetes care. Sanofi has played an active role as a long-standing partner in this program since its inception. The continuity of this partnership has contributed to the value and reputation that the [named awards programme] has in the community. Categories and criteria within categories have remained largely stable over many years, updated according to the opinion of long-standing steering committee members holding senior positions in the NHS. Discussion to agree winners of categories is held openly and transparently within a multidisciplinary panel of judges. Based on this, and the robust and transparent process put in place by [the Organiser] and interview statements by judges, Sanofi do not believe that we have special influence in choice of categories or award winners or that the recent awards have been newly and specially aligned to Type 1 Diabetes. The awards given and the judges comments do not directly or indirectly reference Sanofi's prelicence medicine and therefore Sanofi refutes the suggestion that any disguised or prelicence promotion of teplizumab has taken place through its sponsorship of these awards.

Sanofi strongly believes that its involvement in the Diabetes [named awards programme] awards was appropriate and ethical and we deny any breaches of clauses 5.1 and 15.6.

The signatory for the certified items attached are [signatory name and qualifications] and [signatory name and qualifications].

If you require any further information to assist your preparation of this case, please contact us."

PANEL RULING

This complaint was in relation to a diabetes awards programme, part of which was an awards presentation event sponsored by Sanofi. The event was organised by a media company, specialising in the healthcare sector ("the Organisers"). The Organisers had created awards programmes in several therapeutic areas (including diabetes), to recognise good practice in patient care and joint working in key therapy areas and to share the projects and initiatives through its publications and multi-channel communications. Sanofi had been the sole industry sponsor for the diabetes awards programme since its inception in 2011.

The complainant was an attendee at the diabetes awards event and the Panel interpreted their complaint to comprise two allegations:

1. Sanofi's level of involvement was such that the impartiality of the awards was in question and that it had leveraged its position as a sponsor to bias the awards towards initiatives and individuals associated with Type 1 diabetes care in preparation for the launch of teplizumab. This was an alleged failure to maintain high standards (in breach of Clause 5.1).
2. Sanofi had used the awards presentation event for the disguised promotion of the forthcoming launch of its product, teplizumab (in breach of Clause 15.6).

Allegation 1 – Sanofi had leveraged its position as sponsor to bias the awards towards initiatives and individuals aligned to Type 1 diabetes care (Clause 5.1)

This allegation was that Sanofi had used its sponsorship to bias the awards towards initiatives and individuals associated with Type 1 diabetes care where it had a particular commercial interest. The Panel noted that Sanofi was an established presence in the diabetes market with products for the management of both Type 1 and Type 2 diabetes.

The Panel interpreted the allegations as not relating to the agenda, nor to the arrangements for the awards presentation event, and therefore the Panel did not consider these aspects.

In considering this specific allegation, the Panel took account of:

- the sponsorship contract,
- the level of influence and involvement Sanofi had in the awards programme (and specifically in relation to award categories and judging), and
- the impression created for attendees at the awards presentation event.

The Panel considered the judging process in which the judging panel comprised 31 individuals who were diabetes health professionals, patient representatives, patient organisations and also included three Sanofi employees. The Organisers allocated judges to one of three panels of ten with each group including a Sanofi employee. Each panel was allocated entries which were then assessed and scored by each judge individually with completed scorecards and justifications submitted to the organisers prior to a plenary discussion to decide on the winners for each category. To ensure transparency at the plenary discussion every judge's scores were visible to the other judges on the panel. The Panel considered that, on the evidence before it, the judging process appeared to be sufficiently robust to ensure that the Sanofi judges could not exert undue influence over which initiatives won particular categories.

With regard to the award categories, two categories related specifically to Type 1 diabetes, one of which was a specific award for "Type 1 Specialist Service." Whilst there was no award category specifically for Type 2 diabetes, the Panel acknowledged that other categories could have considered entries about Type 2 diabetes initiatives.

The Panel had no information relating to the entries received for each award category. However, Sanofi submitted that the Organisers had analysed the award submissions overall and reported that:

- 52% of submissions related to Type 1 diabetes,
- 21% to Type 2 diabetes,
- 7% to Type 1 and 2 diabetes, and
- the remainder (30%) did not indicate a particular subset of diabetes care.

Sanofi further submitted that none of the awards related to projects which directly or indirectly referenced teplizumab, nor were in the patient population for teplizumab (i.e. adults and children with stage 2 Type 1 diabetes).

Sanofi's response indicated that the categories of awards were reviewed and agreed each year by a steering committee comprising four members, one of which was a Sanofi employee. This group reviewed the categories to ensure their relevance to the evolving NHS environment and assessed the judging criteria which, for 2024, were amended to include "impact to patients".

Whilst the sponsorship agreement gave Sanofi the opportunity to be engaged and consulted at all appropriate stages to make recommendations and shape the future development of the awards programme in diabetes, the Panel accepted that the award categories had been largely consistent over the previous five years. The Panel concluded that it did not have evidence before it to establish that Sanofi had leveraged its sponsorship to influence the categories of awards in 2024.

Noting the complainant's general concern that Sanofi's sponsorship impacted the impartiality of the awards programme, the Panel considered the overall impressions to potential entrants, key stakeholders in diabetes care and attendees.

The Panel took account of the following factors from the sponsorship contract:

- It specified exclusivity for Sanofi for sponsoring the awards programme and presentation event.
- Sanofi fully funded the awards programme including providing the venue for the awards presentation event (Sanofi's head office).

- Sanofi had a noticeably close relationship with the awards programme and presentation event in having input/influence on shaping the awards programme, the judging criteria, taking part in judging awards entries and in contributing to editorial content.
- Sanofi staff members could attend programme events during the year. In this case, 23 Sanofi staff members attended the awards presentation event which had two networking opportunities with key stakeholders in diabetic care.
- Invited guests (including stakeholders in diabetes) were agreed with Sanofi in advance.
- Sanofi's logo was placed on all materials relating to the event.
- Sanofi contributed to the Organiser's editorial content.

The Panel had been provided with the back page of the programme for the awards presentation event which included the declaration of involvement: "*Sanofi UK is privileged to support the fourteenth [diabetes awards] that recognises, rewards and shares good practice in diabetes.*"

While there could be no doubt that Sanofi had been involved, the Panel was concerned whether attendees at the awards presentation event would be aware of the significant level of involvement and influence Sanofi had over the awards programme. In this regard, the Panel noted that transparency was a key principle underpinning the Code.

The Panel considered that the overall impression of the awards presentation event was such that some attendees could be confused about the ownership of the event. Taking all of these factors into account, the Panel determined that the nature and level of Sanofi's involvement and influence in the awards presentation event was not sufficiently clear and, in this respect, high standards had not been maintained. The Panel ruled a **breach of Clause 5.1**.

Allegation 2 – disguised promotion of teplizumab at the awards presentation event (Clause 15.6).

The Panel considered the allegation that Sanofi had used the awards event to align itself with Type 1 diabetes and thus prepare for the launch of teplizumab (a pipeline product that was not licensed in the UK at the time) and that therefore the event was disguised promotion for teplizumab.

The Panel took account of the broad definition of promotion in Clause 1.17 of the Code, which referred to any activity which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The Panel also considered that it was an accepted principle under the Code that it was possible (given the broad definition of promotion), for material to be promotional without mentioning products by name.

In response to this allegation, Sanofi submitted that none of the awards related to projects which directly or indirectly referenced teplizumab, nor were in the patient population for teplizumab (delayed onset of stage 3 Type 1 diabetes in adults and children with stage 2 Type 1 diabetes).

The Panel considered Sanofi's input and presence at the event, including the briefing document that Sanofi provided to its 23 members of staff that attended the event, which stated: "*you are also reminded that this is a non-promotional meeting, and your discussions with guests must remain non-promotional in nature*" and "*if a guest proactively asks about a Sanofi product or promotional activity please advise them that you are attending in a non-promotional capacity and therefore not able to discuss anything related to Sanofi products. If a guest proactively*

initiates a discussion around Sanofi products or promotional activities, advise them you are unable to enter into promotional discussions at this meeting.”

The briefing document also provided staff with an agenda, which included two opportunities for networking between Sanofi staff and key stakeholders at 18:00 for one hour and then again at 20:00 for one hour. The Panel had no evidence before it in relation to what discussions had taken place between Sanofi staff and stakeholders during these networking opportunities.

Considering the sponsorship agreement and award winner summaries, the Panel observed that the event was promotional of Sanofi from a corporate perspective. However, the Panel was not satisfied that there was evidence of the event being promotional of teplizumab. The complainant had therefore failed to discharge their burden of proof in relation to this allegation.

Given the narrow nature of the disguised promotion allegation, and the Panel’s conclusion of the event not being promotional of teplizumab, the Panel concluded that promotion could not have been disguised and therefore ruled **no breach of Clause 15.6**.

APPEAL BY SANOFI

Sanofi’s written basis for appealing is reproduced below.

“Sanofi acknowledges the PMCPA’s rulings of no breach of Clause 15.6 of the 2021 ABPI Code of Practice (the Code) in relation to AUTH/0363/11/24. However, Sanofi refutes the breach of Clause 5.1. Sanofi is committed to adhering to both the letter and the spirit of the Code and all other relevant UK rules and regulations. Sanofi believes that it has maintained high standards with respect to the activity in question.

Rationale for Appeal

Sanofi understands that the Panel ruled a breach of Clause 5.1 because:

.....the Panel was concerned whether attendees at the awards presentation event would be aware of the significant level of involvement and influence Sanofi had over the awards programme. In this regard, the Panel noted that transparency was a key principle underpinning the Code.....Sanofi’s involvement and influence in the awards presentation event was not sufficiently clear

In the original complaint, Sanofi defended that it had unduly leveraged its position as sponsor to sway the choice of awards over the months preceding the event. In this ruling, the Panel was concerned that there had been insufficient transparency at the awards presentation event itself. Sanofi is extremely concerned that a breach of Clause 5.1 was awarded on the above basis given that:

1. The transparency of Sanofi’s involvement in the awards presentation event did not form part of the original complaint. It is therefore unacceptable to adjudicate on this basis.
2. Given the wording in the original complaint, there can be little doubt that Sanofi’s involvement in the awards was clear to attendees, as acknowledged by the Panel in its ruling.

3. Sanofi was not asked to provide information on its involvement in the awards presentation event in the original letter from the PMCPA.
4. The PMCPA is not an investigatory body and Sanofi believe it has operated beyond its remit.

Sanofi took substantial care to be transparent regarding its involvement and although this information was not requested in the original matter, it is happy to provide details to support the Appeal Board's understanding of the steps Sanofi took to ensure its involvement in the awards presentation event was transparent:

- The annual [named awards programme] diabetes awards evening event is held at Sanofi's UK office. This was detailed on the invitation and the company name is in large letters on the front of the building.
- An awards booklet was placed on every seat before the awards ceremony, ensuring every attendee received a copy of the booklet
- The front page of the booklet included the Sanofi logo prominently in the top right -hand corner with the statement 'Sponsored by Sanofi'. The bottom of the front page included the following statement:

The [named awards programme] Diabetes programme has been made possible with sponsorship from Sanofi. Sanofi has had no editorial control over any of its contents.

- The fourth page of the booklet was titled 'Programme Partner' and included the picture, name and job title of the [named senior medical employee] alongside the following text:

Sanofi is proud to be the sponsor of [named awards programme] Diabetes and support this programme that is dedicated to recognise, share and reward excellence in diabetes care.

Sanofi is an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and potentially life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the centre of our ambitions.

"Sanofi is delighted to support the [named awards programme] Programme in 2024 and to recognise and reward the innovations that will benefit people living with diabetes. The [named awards programme] is at the forefront of sharing best practice to improve the quality of care, through demonstrating novel solutions to problems encountered by health care professionals and those impacted by diabetes on a daily basis."

- Pages 12-22 include the pictures and biographies of the judging panel, listed alphabetically. The pictures and biographies of the three Sanofi judges are

included in this list; the biographies make specific reference to their role and employment at Sanofi.

- Page 37 is an acknowledgement page – Sanofi is acknowledged as a Programme Partner with a clear logo which sits above the logos of the ‘Supporters’.
- Pages 38-39 include the guest list, with names listed alphabetically; Sanofi attendees are listed by name and company affiliation (Sanofi)
- Page 40 - the back page - consists of an image which occupies approximately a third of the page, a prominent Sanofi logo at the bottom of the page, and the following statement which takes up the remainder of the page:

Sanofi UK is privileged to support the fourteenth [named awards programme] Diabetes Awards that recognises, rewards and shares good practice in diabetes.

Congratulations and good luck to all finalists!

- At the beginning of the awards ceremony, the Master of Ceremonies, an HCP and broadcaster who has no affiliation with Sanofi, made the following introduction
Not forgetting our programme partner and this evening’s hosts, Sanofi and I am delighted to welcome [a senior leader] at Sanofi UK & Ireland, [name of senior leader] to the stage.
- Sanofi’s [senior leader] welcomed attendees to the event. [They] also closed the event by thanking the attendees.
- The awards were presented by a variety of individuals, including HCPs, a member of a communications agency, a member of a patient organisation and two Sanofi employees. All presenters were welcomed to the stage by name, job title and company/affiliation

In summary:

- the awards were hosted in Sanofi offices, which are clearly signposted before entering the building and within the building,
- the programme clearly stated Sanofi as a programme partner on the front page, back page and throughout the awards booklet,
- the Sanofi judges’ names, pictures and affiliations were included in the programme,
- the Sanofi attendees were included in the attendee list,
- Sanofi employees who took an active part in the presentation of the awards were clearly identified.

The involvement by Sanofi as a sponsor is unambiguous. We consider that there was appropriate transparency regarding Sanofi’s involvement and influence in the awards ceremony and that high standards were maintained. We therefore refute and appeal the breach of Clause 5.1 in this regard.

The PMCPA is not an investigatory body

The PMCPA asked Sanofi to respond to the following complaint:

- *Sanofi’s level of involvement was such that the impartiality of the awards was in question and that it had leveraged its position as a sponsor to bias the awards*

towards initiatives and individuals associated with Type 1 diabetes care in preparation for the launch of teplizumab. This was an alleged failure to maintain high standards (in breach of Clause 5.1).

- *Sanofi had used the awards presentation event for the disguised promotion of the forthcoming launch of its product, teplizumab (in breach of Clause 15.6).*

The panel ruled that there was no evidence either that Sanofi had exerted undue influence on the awards, had leveraged its sponsorship to influence the categories, or that it has used the awards presentation event for the disguised promotion of teplizumab.

Sanofi is therefore concerned that the PMCPA ruled on a matter that was not raised by the complainant either specifically, or by inference. Given that the PMCPA Constitution stipulates that is not an investigatory body, Sanofi asserts that this ruling falls outside the scope of the PMCPA's jurisdiction and therefore the breach of Clause 5.1 should not have been awarded.

Sanofi is committed to fully adhering to the letter and spirit of the Code and to consistently upholding the highest standards in all our activities.”

RESPONSE FROM THE COMPLAINANT

The complainant was not contactable.

APPEAL BOARD RULING

The Appeal Board considered that Sanofi had ample opportunity to address the complainant's allegations.

The Appeal Board considered the basis on which the Panel made its Clause 5.1 ruling was within the scope of the original complaint, because the issue of transparency is inextricably linked to the perception the complainant had that Sanofi was leveraging the event and seeking to disguise promotion through a non-promotional event. Given that Sanofi was the sole funder/sponsor of the awards event, and in order to avoid the perception of seeking to disguise promotion through a non-promotional event or undue leveraging of the event, the Appeal Board considered that complete and unambiguous transparency was essential.

The Appeal Board in particular took note of the difference between sole sponsorship where the involvement of the sponsor company was clear throughout, and sponsorship in this case of an awards event where Sanofi's involvement in the actual awards was far less transparent.

The Appeal Board noted some examples of where Sanofi's involvement may not have been sufficiently clear to attendees:

- Sanofi staff represented 25% of the steering committee which decided on the award categories
- Sanofi staff made up nearly 10% of the total number of judges

While it was clear that Sanofi was involved in the event, the Appeal Board concluded that the exact nature and extent of that involvement would have been unclear to attendees. The Appeal Board concluded that Sanofi had failed to maintain high standards and upheld the Panel's ruling of a breach of Clause 5.1. The appeal was unsuccessful.

Complaint received **15 November 2024**

Case completed **7 January 2026**