**CASE/0518/03/25**

# PFIZER v SANOFI

## Allegations about a global senior leader's interview in the Observer

### CASE SUMMARY

**This case was in relation to an article in a UK Sunday newspaper that was based on an interview with a Sanofi global senior leader. In addition to being a 'Profile' piece about the individual, the article also reported on topics related to Sanofi, including its respiratory syncytial virus (RSV) vaccine - Beyfortus (nersevimab-alip). Pfizer alleged that the article promoted Beyfortus to the public, included unbalanced and misleading claims, and disparaged Pfizer's vaccine.**

**The outcome under the 2024 Code was:**

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| **Breach of Clause 2** | **Bringing discredit upon, and reducing confidence in, the pharmaceutical industry** |
| **Breach of Clause 5.1** | **Failing to maintain high standards** |
| **Breach of Clause 6.1(x2)** | **Making a misleading claim** |
| **Breach of Clause 6.2(x2)** | **Making an unsubstantiated claim** |
| **Breach of Clause 6.6** | **Disparaging another company's medicine** |
| **Breach of Clause 26.1** | **Advertising a prescription only medicine to the public** |
| **Breach of Clause 26.2(x3)** | **Providing unbalanced information and encouraging members of the public to ask for a specific prescription only medicine** |

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

### FULL CASE REPORT

An intercompany complaint about Sanofi was received from Pfizer Limited.

### COMPLAINT

The complaint wording is reproduced below:

> "Pfizer has serious concerns regarding an interview with Sanofi's [named global senior leader], published in the Observer newspaper on 13th October 2024 which promoted Sanofi's monoclonal antibody product (Beyfortus) to the public, made unsubstantiated comparative claims, promoted relative efficacy data without reference to absolute

efficacy or the relevant safety information and disparaged the Government's national immunisation programme and Pfizer's vaccine.

Given the seriousness of this case, we respectfully request that this complaint featuring a high-profile newspaper article, containing comments by the [named global senior leader], is taken up by the PMCPA Director as a matter of urgency with an expedited review. In our final intercompany dialogue with Sanofi UK on 19th February 2025, notwithstanding Pfizer's serious concerns, they would not confirm that there would be no further articles of this nature in the coming days and weeks, and therefore any delay may lead to publications of further promotional and misleading articles intended to undermine public confidence in the UK vaccination programme. As a minimum we would ask that the PMCPA requests that Sanofi ceases communicating such articles with immediate effect whilst the panel reviews the case.

By way of context, the UK's national immunisation programme (NIP) to help protect newborns and infants from Respiratory Syncytial Virus (RSV) infection and hospitalisation, is a maternal vaccination programme from 28-36 weeks of pregnancy using Pfizer's RSV Vaccine (Abrysvo). This programme was recommended by the Joint Committee on Vaccination and Immunisation (JCVI) and the NIP was awarded to Abrysvo by the UK Health Security Agency. The UK maternal vaccination programme commenced in September 2024. In several European countries, including Ireland and Spain, the national immunisation programme takes a different approach and employs passive immunisation of newborns using Sanofi's monoclonal antibody product (Beyfortus) rather than a maternal vaccination programme.

Pfizer UK commenced intercompany dialogue with Sanofi UK in October 2024 having become aware of the interview with their [named global senior leader] published in the Observer newspaper. The Observer article made claims about the impact of Sanofi's monoclonal antibody product (Beyfortus) on infant RSV hospitalisation rates in Spain as follows (claims are in bold and italics):

***In Spain Beyfortus reduced RSV hospitalisation by 82% in babies less than 6 months old, according to results from the first RSV season last winter, after the drug's launch.***

This is a promotional efficacy claim for Beyfortus and promotes a Prescription Only Medicine to the public in breach of clause 26.1 of the Code. Furthermore, the claim states a relative risk reduction with no indication of the absolute risk reduction and is not balanced with any relevant safety information, in breach of clauses 6.1 and 26.2 of the Code. Pfizer believes that the inclusion of this inappropriate promotional statement in the published article was a direct result of comments made by the [named global senior leader] which highlighted these data to the journalist.

***[Named global senior leader] argues that Beyfortus is more effective than a vaccine invented by US rival Pfizer, which is given to pregnant women who develop antibodies that protect the baby. There are no studies evaluating this, but [they] note that 'maternal vaccines have a very low uptake'.***

This inaccurate and misleading superiority claim which is attributed to the [named global senior leader], does not reflect the available evidence and cannot be

substantiated. Pfizer believes this statement represents a breach of clauses 6.1 and 6.2 of the Code and we can only draw the conclusion that the statement was intended to encourage members of the public to ask their health professional to prescribe Beyfortus, a breach of clause 26.2.

***The UK has become the first country in the world to develop a national vaccination programme for RSV, which [they] applaud. However, the government opted for the cheaper Pfizer jab. 'It's a financial choice,' [named global senior leader] says. 'If you're choosing for a clinical benefit, you would choose Beyfortus.'***

This is again a superiority claim that is incapable of substantiation and disparages Pfizer's vaccine, in breach of clauses 6.2 and 6.6 of the Code. The statement is intended to encourage members of the public to ask their health professional to prescribe Beyfortus, in breach of clause 26.2. Through the unsubstantiated suggestion that the Government has selected a clinically inferior product on the basis of cost, [named global senior leader] has risked undermining the national immunisation programme for RSV, an action that is not consistent with the high standards expected of senior leaders in our industry and breaches clause 5.1 of the Code.

The [named global senior leader]'s interview statements raise serious concerns in relation to multiple clauses of the ABPI Code, including promotion of Beyfortus to the public, promotion of unsubstantiated and misleading superiority claims for Beyfortus compared to Pfizer's vaccine, discussion of relative efficacy data without reference to absolute efficacy or relevant safety information, and lastly disparagement of both the Government's national immunisation programme and Pfizer's vaccine. Pfizer believes that this falls far short of the standards expected of a pharmaceutical company as set out in clause 5.1 of the Code and has brought discredit upon and reduced confidence in our industry, a breach of clause 2.

At the start of our intercompany dialogue in October, we spoke to [named senior Sanofi employee] who shared our concerns, but [they] have since left the organisation. In our subsequent intercompany dialogue, we asked that Sanofi write a corrective statement as a letter to the editor of the Observer newspaper, covering the following points:

- There is no scientific or other appropriate basis for the comments attributed to [named global senior leader] that Beyfortus is more effective than the Pfizer RSV vaccine.

- All National Immunisation Programmes by the Government are important for helping to protect public health. This includes the RSV National Immunisation Programme which was awarded to Pfizer.

- Comments made by Sanofi stating that RSV hospitalisations were reduced by 82% in babies less than 6 months old treated with Beyfortus, were inappropriate and misleading.

- Sanofi regrets the comments in the article regarding Pfizer's RSV vaccine.

Instead of making these points to demonstrate mistakes had been made which required correction and offering an apology, Sanofi proposed writing a different letter to the editor which we believe played down the seriousness of the misleading and inappropriate claims and this was not considered by Pfizer as an acceptable corrective statement.

In October Pfizer asked Sanofi how [named global senior leader] was briefed for the interview. Sanofi's response stated that the briefing document prepared for [named global senior leader] did not contain any instructions or requests to discuss Beyfortus. In the final intercompany online meeting on 19th February with Sanofi's [named senior employee], Pfizer questioned again how [named global senior leader] had been briefed. The response was that [named global senior leader] knew these Beyfortus data well and often discussed them with journalists. They said that the [named global senior leader] briefing document prior to the Observer interview did not encourage discussion of these data. However, they were not able to answer whether Sanofi had appropriately governed the obvious risks by ensuring that the briefing document explicitly asked [them] not to talk about Beyfortus and the associated data, given that it was well-known in the company that [they] discussed this with journalists. This unwillingness to answer our question was particularly disappointing given that the intercompany dialogue had been in progress since October when this question was first raised, and the latest discussion was on 19th February when it was raised again.

In February, despite our ongoing intercompany dialogue, Pfizer became aware of two further articles. The first, a Sunday Express article published on 1st February was a promotional article for Beyfortus referring to new data from Ireland as 'stunning' and a 'game-changer'. As in the Observer article, it went on to raise concerns about the UK national immunisation programme and make inappropriate comparisons with Beyfortus programmes in Ireland and other countries which cannot be substantiated with scientific evidence. In the final intercompany online meeting on 19th February with [named senior Sanofi employee], they confirmed that Sanofi UK had been contacted by the journalist and answers to the journalist's questions were provided. Given the nature of the article, the data being quoted and the claims being made were so similar to the Observer article, we believe that Sanofi UK and potentially their public relations agencies provided the same narrative to the Sunday Express journalist as did [named global senior leader] to the Observer journalist.

The second article published on 13th February in the Health Service Journal (HSJ) was a paid article written by the [named senior Sanofi employee]. It highlighted data from the Ireland neonatal immunisation programme using Beyfortus, making inappropriate and disparaging claims against the UK maternal vaccination programme using Pfizer's RSV vaccine and suggesting the UK programme was inferior. It raised concerns that infant RSV hospitalisations in the UK (compared to Ireland) had not decreased this winter compared to last winter despite the UK vaccination programme with Pfizer's RSV vaccine. However, it failed to mention that a maternal vaccination programme launching in September 2024 and administered from 28 weeks gestation, is highly unlikely to show an impact yet on neonatal infections and hospitalisations due to the time lag from maternal vaccination to birth. The article was certified by Sanofi UK for dissemination to HSJ readership and was then amplified through several social media posts by the [named senior Sanofi employee] who authored the article and the [named

senior Sanofi employee]. These posts linked to the article and promoted the article to a wider audience including the general public.

The publication of two further articles making the same inappropriate promotional and disparaging claims that were already the subject of intercompany dialogue, gave Pfizer no alternative than to conclude that Sanofi was not taking Pfizer's concerns seriously. It was clearly apparent that Sanofi had no intention of modifying its behaviour (directly or the behaviour of its public relations agencies) in any way that would allow Pfizer and Sanofi to successfully resolve Pfizer's concerns about alleged breaches of the Code through intercompany dialogue.

Taken together, the [named global senior leader] interview in the Observer, the Sunday Express article, the HSJ article and associated social media posts, represent a deeply concerning concerted attempt to promote Beyfortus to the public, to make inappropriate and unsubstantiated superiority claims against Pfizer's RSV vaccine and to disseminate disparaging messaging to the public regarding the Government's national immunisation programme, alleging that Pfizer's vaccine had been selected only on cost grounds and was clinically inferior to Beyfortus-based programmes in other countries. These activities fail to maintain high standards and bring the pharmaceutical industry into disrepute, in breach of clauses 5.1 and 2."

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 26.2, 26.1, 6.6, 6.2, 6.1, 5.1 and 2 of the 2024 Code.

**SANOFI'S RESPONSE**

The response from Sanofi is reproduced below:

**Pre-response from Sanofi**

"We are writing to formally clarify the scope of our required response to Case AUTH/0518/03/25.

The previous intercompany dialogue relating to this complaint is about an article that was published in the Observer. Sanofi will respond to this complaint by 17th April 2025.

We wish to bring to your attention that Pfizer has included in this complaint two additional articles, published in the Sunday Express article and HSJ. These will not be addressed in our response because we do not consider the intercompany dialogue condition (outlined under Section 5.11 of the PMCPA Complaints Procedure) has been met.

Pfizer first mentioned these articles on 14th February 2025 without any mention of specific clauses alleged to have been breached. Please find enclosed a copy of this email and Sanofi's subsequent response. We do not consider intercompany dialogue to have been attempted properly on these articles.

This is important as the circumstances and particulars of these articles are substantively different to the Observer article. Therefore, in relation to Pfizer's concerns about these articles, in line with the principles of self-regulations, Sanofi would ask that the PMCPA

direct Pfizer to initiate proper intercompany dialogue, before they can be considered as part of a formal complaint.

We would appreciate your confirmation that these two articles (Sunday Express and HSJ) will not be included under this complaint once the Panel convenes to rule.

Thank you for your prompt response on this matter."

**Full response from Sanofi**

"We are writing in response to the above-mentioned complaint. Sanofi takes compliance with the ABPI Code of Practice very seriously, and we appreciate the opportunity to address the concerns raised by Pfizer.

**Background to RSV Prevention Strategies**

Many European countries have implemented a national immunisation programme for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants. Countries such as Ireland and Spain, have chosen the direct immunisation of infants and newborns, while the UK has chosen a maternal vaccination programme.

**Background to the Published Article**

In May 2024, real-world evidence from a longitudinal population-based study from Galicia, Spain published in The Lancet Infectious Diseases showed Beyfortus substantially reduced infant hospitalisation for RSV-associated lower respiratory tract disease infection (LRTI), severe RSV-associated LRTI requiring oxygen, and all-cause LRTI when given in real-world conditions during the 2023-2024 RSV season, versus no intervention.

In August 2024, The Observer requested an interview with [named global senior leader] in relation to the broader challenges facing the pharmaceutical industry in the UK e.g. inward investment. [Named global senior leader] was briefed fully beforehand.

It has long been established that information provided to business and consumer journalists complies with the Code if it is news, newsworthy and relevant for the target readership. This is the **fundamental basis of public relations and arguably** drug pricing, RSV and vaccination are all topics that the public have an interest in.

Pfizer's allegations centre on the [named global senior leader]'s statements about Beyfortus in this interview.

**Response to allegations**

Our response addresses each point highlighted in Pfizer's original complaint letter:

1. *In Spain Beyfortus reduced RSV hospitalisation by 82% in babies less than 6 months old, according to results from the first RSV season last winter, after the drug's launch – alleged breaches of Clauses 6.1, 26.1 and 26.2*

The briefing document prepared for [named global senior leader] focused on the broader RSV landscape and immunisation programs implemented in other countries and the broader UK landscape and it did not contain any directions to discuss Beyfortus. In the context of newsworthy data being shared with the media, it was not

the intent of [named global senior leader] to promote Beyfortus to UK members of the public, especially as Beyfortus cannot be requested or prescribed but to discuss positions taken by other countries.

As per cases AUTH/ 3518/5/21, 3519/5/21 & 3760/4/23, relative risk reduction (RRR) is the standard way for vaccine efficacy to be presented and has been for decades. On the balance of probabilities, it seems very unlikely that some readers might have assumed that the 82% efficacy rate was an absolute rate.
Following the interview Sanofi provided clarified the data and asked the journalist to remove this statement as it was not in line with the brief. The content of the final article was out of our control, as the journalist was the final decision maker.

2. [Named global senior leader] *argues that Beyfortus is more effective than a vaccine invented by US rival Pfizer, which is given to pregnant women who develop antibodies that protect the baby. There are no studies evaluating this, but [they] note that "maternal vaccines have a very low uptake"- alleged breaches of Clauses 6.1, 6.2 and 26.2*

Following the publication of the print article, Sanofi asked the journalist to remove this statement as no head-to-head studies exist. The content of the final article was out of our control, as the journalist was the final decision maker, but they did include our clarification that "*there are no studies evaluating this"*.
It is important to note that this statement was not intended to encourage members of the public to ask their healthcare professional to prescribe Beyfortus as the product is not available in the UK either on the NHS or privately.

3. *The UK has become the first country in the world to develop a national vaccination programme for RSV, which [they] applaud. However, the government opted for the cheaper Pfizer jab. "It's a financial choice,"* [named global senior leader] *says. "If you're choosing for a clinical benefit, you would choose Beyfortus." - alleged breaches of Clauses 6.2, 6.6 and 26.2*

Please see our earlier comments about the briefing document and the intent of [named global senior leader] to discuss positions taken by other countries. Following the publication of the print article, Sanofi asked the journalist to remove this statement for the online article. The content of the final article was out of our control, as the journalist was the final decision maker.

**Daily Express and HSJ Articles**
As stated in our letter dated 10 April 2025, Sanofi maintains that Pfizer has not followed the requirements of the PMCPA Constitution and Procedure by failing to engage in proper intercompany dialogue regarding these additional articles. We believe Pfizer should have given Sanofi the opportunity to discuss these concerns directly before escalating to the PMCPA, as they are not linked to the Observer news article.
Following Sanofi's telephone conversation with the PMCPA on the 16 April 2025, we understand this matter is now being managed separately.

**Intercompany Dialogue Concerns**
In addition to the comments concerning intercompany dialogue above, Sanofi also does not believe that the intercompany dialogue process was exhausted in the

Observer article discussion to warrant escalation to the PMCPA. We prepared a draft 'Letter to Editor' expecting collaborative refinement from Pfizer. Instead, they simply restated their original points, which was unsuitable for the intended format. We believe continued engagement could have resolved this matter in the spirit of self-regulation without requiring PMCPA intervention.

**Remedial Actions**
Sanofi has a strong compliance culture, and we believe in maintaining high standards in all we do. We will take this opportunity to reinforce our culture even further and we have already taken a number of key learnings and implemented the following additional measures to prevent similar occurrences:

- All corporate briefings for senior leaders will contain explicit reference to the ABPI Code of Practice and that no promotional claims concerning Sanofi products can be made
- All corporate briefings for senior leaders will now be examined, regardless of purpose
- A medical signatory will sit in all UK media interviews to ensure that any potential Code breach can be immediately addressed
- Implementation of clearer protocols for managing journalist interactions post-interview
- Additional media training for senior executives, who reside outside of the UK but engage with the UK media, focusing specifically on Code compliance

**Conclusion**
In summary, Sanofi had no intention of promoting to the public or disparaging any vaccine or immunisation program. We made every effort to ensure the information provided was fair and balanced, though we had limited control of the final article once the journalist had the information. We acknowledge that the interview did not go according to the briefing. However, we believe our compliance preparations before the interview and our prompt corrective actions afterward demonstrate our commitment to ensuring accurate information reaches the public domain.
These proactive measures support our position that clause 2 was not breached. [Named global senior leader]'s intended message was to highlight broader healthcare system access issues in the UK and concerns about the framework for innovation investment."

**PANEL RULING**

This case was in relation to an article in a UK Sunday newspaper that was based on an interview with a Sanofi global senior leader. It was a 'Profile' piece, intended to be about the individual. However, in addition to including information about the global senior leader's background (their education, interests etc), it also reported on topics related to Sanofi including the topic of Beyfortus (nersevimab-alip); Sanofi's respiratory syncytial virus (RSV) vaccine.

**Intercompany dialogue**

Before making a complaint to the PMCPA, Pfizer raised concerns with Sanofi about certain sections of the article via intercompany dialogue, as required by the PMCPA Constitution and Procedure. However, this dialogue had not been successful in resolving the matter and Pfizer referred a complaint to the PMCPA. Although two further articles were referred to in the

complaint, the case preparation manager, in accordance with the Constitution and Procedure, concluded that the article in the Observer was the only article at the time that met the criteria for being referred to the Panel as an intercompany dispute.

**The complaint**

The Panel interpreted Pfzier's complaint to allege that it had concerns about three claims which appeared in three consecutive paragraphs in the Observer article. The Panel considered each of these three claims in turn.

Claim 1

The claim was:

> "*In Spain, Beyfortus reduced RSV hospitalisations by 82% in babies less than six months old, according to results from the first RSV season last winter, after the drug's launch."*

Pfizer alleged that this was a promotional statement that appeared in the article due to answers given by the global senior leader in their interview, and that it:

1. Was an efficacy claim that promoted Beyfortus to the public (in breach of Clause 26.1).
2. Referred to relative risk reduction without reference to the absolute risk reduction and was not balanced and did not include relevant safety information (in breach of Clauses 6.1 and 26.2).

Claim 2

The claim was:

> *"[Global senior leader] argues that Beyfortus is more effective than a vaccine invented by US rival Pfizer, which is given to pregnant women who develop antibodies that protect the baby. There are no studies evaluating this, but [they] note that "maternal vaccines have a very low uptake"."*

Pfizer alleged that this claim, attributed to the global senior leader, was:

1. An inaccurate and misleading superiority claim, that did not reflect the available evidence and could not be substantiated (in breach of Clauses 6.1 and 6.2).
2. Intended to encourage members of the public to ask their health professional to prescribe Beyfortus (in breach of Clause 26.2).

Claim 3

The claim was:

> *"The UK has become the first country in the world to develop a national vaccination programme for RSV, which [the global senior leader] applauds. However, the government opted for the cheaper Pfizer jab. "It's a financial choice," [global senior leader] says. "If you're choosing for a clinical benefit, you would choose Beyfortus.""*

Pfizer alleged that this claim, which included quotes from the global senior leader, was:

1. A superiority claim that was incapable of substantiation (in breach of Clause 6.2).
2. Disparaging of Pfizer's vaccine (in breach of Clause 6.6).
3. Intended to encourage members of the public to ask their health professional to prescribe Beyfortus (in breach of Clause 26.2).

High standards and bringing discredit upon the industry.

Pfizer also alleged that, by making an unsubstantiated suggestion that the Government had selected a clinically inferior product on the basis of cost, the global senior leader had risked undermining the national immunisation programme for RSV. Pfizer considered this to be inconsistent with the high standards expected of senior leaders and alleged a breach of Clause 5.1.

In addition, Pfizer alleged that all of its allegations above amounted to an additional breach of Clause 2 for bringing discredit upon, or reducing confidence in, the pharmaceutical industry.

**Sanofi's response**

Sanofi's response to this complaint was that the briefing document it provided to its global senior leader did not contain any direction to discuss Beyfortus and nor was any briefing given to the journalist.

Sanofi acknowledged that the interview did not go according to the briefing but submitted that there was no intention to promote to the public or disparage any vaccine or immunisation program. It also pointed out that Sanofi had limited control over how the journalist chose to translate the interview into a published article.

It was clear from the documents provided by Sanofi in response to this complaint that the journalist had emailed Sanofi after the interview had taken place (on the Thursday before the Sunday publication) to ask some follow-up questions of Sanofi before finalising the article. The journalist's email to Sanofi asked "*[Global senior leader] said Beyfortus (which is an antibody rather than a vaccine) is more effective than Pfizer's Abrysvo – are there any studies that show this?*"

Sanofi responded with a document that stated that a direct comparison of the effectiveness of the two products was not possible because there was no head-to-head study available. However, the document went on to state:

> "*According to the interim results of an ongoing three-year NIRSE-GAL study conducted in Galicia, Spain and published in The Lancet, in 2023/24 RSV season, the authors estimate a reduction in RSV-related LRTI hospitalisation of 82% (95% CI 65.6-90.2) in immunised groups (seasonal, catch up and high risk) compared to previous years.*"

Sanofi also provided an email showing that, on the Monday morning after the Sunday print version of the article had been published, it had attempted to have the comparison statement (*"[Global senior leader] argues that Beyfortus is more effective than a vaccine invented by US*

*rival Pfizer*") removed from the online version of the article but that the journalist had rejected its request.

**The Panel's conclusions**

General points

The Panel bore in mind that it was an established principle that complaints about independently published articles were judged on the material provided by the company to the journalist, including what was actually said by the interviewee. In relation to the latter, a transcript of the interview and briefing material provided by the company to the interviewee were relevant. The Panel had not been provided with an interview transcript in this case.

Claim 1

The Panel observed that this claim was not published as a direct or indirect quote from the global senior leader but had been lifted from a trial data document sent to the journalist (unlike Claims 2 and 3).

The Panel accepted Sanofi's submission that it had not briefed the journalist in advance of the interview on any topic. Sanofi's pre-interview briefing for its global senior leader provided three 'key messages to land'. The Panel acknowledged that proactive discussion of Beyfortus was not a key message to land. However, the briefing did include five additional key messages and proof points. The fourth additional key message read "*Broadening our view of value when determining cost-effectiveness (eg RSV decision)*" and included the statement:

> "*Real-world evidence from countries implementing national all-infant RSV immunisation programmes show a substantial reduction in hospitalisations.*
>
> *o Over 80% reduction in RSV-related hospitalisation in immunised groups compared to previous years is estimated (interim results of an ongoing study conducted in Spain).*"

Given that there was no transcript of the interview itself, it was difficult for the Panel to determine what exactly the global senior leader had said during the interview.

However, the email exchange between the journalist and Sanofi after the interview (but before the Sunday publication of the article) demonstrated to the Panel that, on balance, the global senior leader must have alluded to the 82% claim or something closely similar in the interview and it was then confirmed to the journalist in a trial data document, partially reproduced above, which was attached to a follow-up email from Sanofi. It therefore follows that Sanofi was responsible for the wording used by the journalist in Claim 1.

Clause 26.1 of the Code stated: "*Prescription only medicines must not be advertised to the public.*"

The Panel concluded that Claim 1 ("*In Spain, Beyfortus reduced RSV hospitalisations by 82% in babies less than six months old, according to results from the first RSV season last winter, after the drug's launch")* was clearly promotional of a prescription only medicine given its inclusion of the brand name (Beyfortus), the indication (RSV), and a claim to reduce hospitalisations by a large percentage. The Panel therefore ruled a **breach of Clause 26.1** in relation to Claim 1.

The Panel considered Clause 6.1 and its supplementary information which highlighted relative risk as an area where care was needed because a reference to relative risk in isolation can make a medicine appear more effective than it actually is. In particular, the supplementary information stated "*relative risk should never be referred to without also referring to the absolute risk.*"

In the Panel's view, this claim referred to relative risk without any reference to absolute risk data. It did so because of an interview and follow-up document that Sanofi had provided to the journalist. It was therefore foreseeable that a relative risk rate would be published in a national Sunday newspaper, without any further trial detail or explanation to contextualise the relative risk rate cited. It was likely that some readers might have mistakenly assumed that the efficacy rate was, in effect, an absolute rate. In relation to Claim 1, the Panel therefore ruled a **breach of Clause 6.1**.

In relation to the allegation that Claim 1 was not balanced with any relevant safety information, the Panel noted that neither the briefing document, nor the email attachment sent to the journalist, referred to safety aspects of the medicine. The Panel considered that this omission was relevant, given that referring to the medicine was an additional key message in the briefing document and the ultimate audience was the general public. The Panel therefore considered that references to the medicine were not balanced and there was a failure to provide relevant safety information. On that basis, the Panel also ruled a **breach of Clause 26.2** in relation to Claim 1.

Claim 2

This claim referred to the global senior leader arguing that Beyfortus (which is administered to babies) is more effective than Pfizer's vaccine (which is administered to pregnant women) and that although there are no studies evaluating this, the global senior leader is quoted as saying *"maternal vaccines have a very low uptake"*.

The Panel accepted that Sanofi had (on the Monday morning after the printed version of the article had been published on Sunday) attempted to have this claim removed from the online version of the article. However, the journalist had declined to remove or change it.

It was clear to the Panel that Claim 2 had been written by the journalist, based on a quote given by the global senior leader. Sanofi accepted that this comparison (of its vaccine being "*more effective*" than Pfizer's) had been made.

The Panel referred to the following extracts from the Code:

1. Clause 6.1 required claims to be "*accurate*", "*based on an up-to-date evaluation of all the evidence*", and "*they must not mislead*".

2. Clause 6.2 required that claims "*must be capable of substantiation*".

3. Clause 26.2 required "*Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine*."

The Panel did not consider that a vaccine's effectiveness could be determined from the level of uptake (as potentially implied by Claim 2). The Panel concluded that such a favourable and direct comparison with a competitor would (even if Beyfortus was not available in the UK at the time) be likely to result in members of the public being encouraged to ask their health professional to administer Beyfortus.

In the absence of any data including direct comparative studies to evidence that Sanofi's vaccine was "*more effective*" than Pfizer's, the Panel concluded that Claim 2 was not accurate, was not based on evidence, and was a misleading superiority claim that could not be substantiated. The Panel therefore ruled **breaches of Clauses 6.1, 6.2 and 26.2** in relation to Claim 2.

Claim 3

As with Claim 2, Claim 3 also included a quote attributed directly to the global senior leader. The Panel interpreted this claim to be that the UK Government had chosen to prioritise cost ahead of clinical effectiveness when choosing Pfizer's vaccine instead of Sanofi's, as part of the NHS vaccination program.

The Panel relied on the extracts of Clauses 6.2 and 26.2 of the Code referred to in Claim 2 above. It also considered Clause 6.6 of the Code: "*The medicines, products and activities of other pharmaceutical companies must not be disparaged.*"

It was clear to the Panel that Claim 3 was a claim of superiority over (and was disparaging of) Pfizer's vaccine. The Panel particularly bore in mind the claim "*If you're choosing for a clinical benefit, you would choose Beyfortus"* The implication, to the Panel, was that the UK Government had chosen a clinically inferior product based only on cost.

The Panel noted in particular that the wording of the claim "*If you're choosing for a clinical benefit"* was likely to encourage a member of the public to ask their health professional to prescribe the product.

The Panel bore in mind that there were no studies evaluating the comparative superiority claim and it therefore concluded that this was a claim that could not be substantiated. This was in addition to the clear disparaging of another pharmaceutical company's product and the encouragement to the public to ask their health professional in relation to the alleged clinical benefit of Beyfortus.

The Panel therefore ruled **breaches of Clauses 6.2, 6.6 and 26.2** in relation to Claim 3.

High standards and bringing discredit upon the industry.

The Panel took account of the context of this complaint - it was an interview with a global senior leader by a major, national Sunday newspaper that would have a wide readership of members of the public. It was therefore critical that the global senior leader exercised caution given the interview topics could range from their hobbies on the one hand, to being asked about prescription only medicines on the other. Companies should bear in mind the weight attached to public comments by their global senior leaders.

In that high profile context, the Panel was concerned that Sanofi had not provided a transcript which would have assisted the Panel in this case.

The Panel considered that the briefing Sanofi had provided to the global senior leader was insufficiently robust in relation to the Code and the potential lines of questions from the journalist. The briefing did not refer to any Code requirements, including the prohibition on promoting prescription only medicines to the public. Whilst the Panel recognised that this was a business corporate 'profile' piece in relation to the individual, the Panel would have nonetheless expected to see some wording in the briefing, advising the global senior leader to be cautious when talking about vaccines, particularly when that article was likely to be published in the lay press with a broad readership.

In relation to Claim 1, the Panel noted that Sanofi had reinforced the 82% claim, by providing a document with more information on that figure after the global senior leader had mentioned it in the interview. This demonstrated to the Panel an intention to ensure that this claim made it into the published article.

In relation to Claims 2 and 3, the Panel considered these to be very bold and unequivocal claims that were neither caveated nor substantiated. In conclusion, the Panel felt that Sanofi had failed to maintain high standards in this case and ruled a **breach of Clause 5.1.**

The Panel was also concerned about these bold claims having the effect of undermining the UK Government's vaccine programme by suggesting (in no uncertain terms) that a procurement choice had been made to prioritise a low price ahead of clinical efficacy. The Panel viewed this as a potential public health concern in the national context of a declining uptake of vaccines. The Panel also noted that Claim 2 referred to vaccines and their low uptake in pregnancy; an area where caution should always be exercised. The Panel viewed the claims as inviting comparison by the public, in the absence of comparative data.

For all these reasons, the Panel concluded that Sanofi's actions had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel ruled a **breach of Clause 2**.

**Complaint received** **20 March 2025**

**Case completed** **17 December 2025**