INTERIM CASE REPORT

An interim case report has been published in this case as the final report was delayed because the Appeal Board decided, in accordance with Paragraph 13.4 of the PMCPA Constitution and Procedure, that Sanofi should be invited to attend the Appeal Board meeting on 15 October 2026 to provide a copy of its third-party audit report and to inform the Appeal Board of progress and action taken as a result of that audit. The Appeal Board reserved its position regarding the application of additional sanctions until consideration of this information at the 15 October 2026 Appeal Board meeting.

CASE/0689/08/25

PFIZER v SANOFI

Allegations regarding articles in the Sunday Express and the Health Service Journal (HSJ) and regarding two social media posts

CASE SUMMARY

This case was in relation to an article in the Sunday Express, an article in the Health Service Journal and two social media posts by Sanofi employees about immunisation programmes for the respiratory syncytial virus (RSV).

Pfizer's RSV vaccine (that is administered to pregnant mothers) had been chosen for the UK's national immunisation programme. Sanofi's product, Beyfortus (nirsevimab), that is administered to neonates, infants and children up to 24 months if certain conditions are met, had been chosen as the medicine for RSV in national immunisation programmes in other European countries.

In relation to the articles and social media posts, Pfizer alleged that Sanofi was responsible for misleading claims and unsubstantiated comparisons about the two medicines, and disparagement of the Pfizer vaccine.

The outcome under the 2024 Code was:

Breach of Clause 2 (x3)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x3)	**Requirement to maintain high standards at all times**
Breach of Clause 6.1 (x3)	**Requirement that Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence**

	clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis
Breach of Clause 6.2 (x3)	**Requirement that information, claim or comparison must be capable of substantiation**
Breach of Clause 6.6 (x3)	**Requirement that another company's medicines must not be disparaged**
Breach of Clause 8.1 (x2)	**Requirement to certify promotional material**
Breach of Clause 26.1 (x2)	**Requirement not to advertise prescription only medicines to the public**
Breach of Clause 26.2 (x2)	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine.**

No Breach of Clause 8.3	**Requirement to certify non-promotional material**

The Panel reported Sanofi to the Appeal Board in accordance with Paragraph 10.2 of the PMCPA Constitution and Procedure for the Appeal Board to decide whether further sanctions were appropriate.

The Appeal Board considered the matter at its meeting in May 2026 and decided, in accordance with Paragraph 13.4 of the PMCPA Constitution and Procedure, that:

(a) the Appeal Board should issue Sanofi with a public reprimand,

(b) Sanofi should be required to provide the Appeal Board with a copy of its third-party audit report and appear at the Appeal Board meeting in October 2026 to provide details of the actions it has taken, and is taking, as a result of the third-party audit, and

(c) the Appeal Board should reserve its decision regarding the application of additional sanctions until consideration of this information.

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 Pfizer.

COMPLAINT

The complaint wording is reproduced below:

> "Following our recent complaint about an article in the Observer featuring an interview with Sanofi's CEO, Pfizer wishes to initiate a second complaint regarding the following two pieces:
>
> - An article in the Sunday Express newspaper on 1st February 2025 for which Sanofi UK provided information to the journalist to answer her questions.
> - A paid for article in the Health Service Journal (HSJ) on 13th February 2025, written by the Sanofi UK General Manager. This article was further disseminated by the General Manager and Medical Lead via social media posts with links to the HSJ article.
>
> As background, these articles discuss distinctly different national strategies for protecting infants against RSV respiratory disease. One involves passively immunizing infants after birth with Sanofi's monoclonal antibody (nirsevimab) and the other involves vaccinating pregnant women to provide protection to infants from birth (Pfizer's maternal RSV vaccine).
>
> The Sunday Express article is a promotional article for nirsevimab, describing new data from Ireland as "stunning" and a "game-changer". It raises concerns about the UK maternal RSV vaccination programme and makes inappropriate comparisons with nirsevimab programmes in Ireland and other countries which cannot be substantiated with scientific evidence. The article completely fails to explain that a maternal vaccination programme launching on 12 August 2024 in Scotland and 1 September 2024 in England and administered from 28 weeks gestation, is highly unlikely to show an impact in that timeframe on neonatal infections due to the time lag from pregnancy to birth. It is therefore scientifically inappropriate and misleading to compare the Irish programme with the UK programme at a timepoint that is significantly biased against the UK programme.
>
> Through intercompany dialogue, Sanofi confirmed that they had been contacted by the journalist and answers to the journalist's five questions were provided. Pfizer requested to see copies of the five questions and the approved answers provided by Sanofi. Although the five questions were provided, Sanofi declined to provide a copy of their approved answers to Pfizer. Without this critical information needed for a proper evaluation, Pfizer and Sanofi agreed on 1st August that intercompany dialogue had failed to resolve the issues in relation to the article.
>
> Given the sensationalist and promotional nature of the article, the data being quoted and the fact that the claims being made are very similar to those in the Observer article, we believe that Sanofi provided a similar narrative to the Sunday Express journalist.
>
> The Sunday Express article is therefore in breach of:
>
> - Clause 26.1 for promoting a POM (nirsevimab) to the public
> - Clause 26.2 for making unbalanced and misleading information available to the public
> - Clause 6.1 for making unbalanced, misleading and inaccurate claims and comparisons

- Clause 6.2 for making claims and comparisons that cannot be substantiated by scientific evidence
- Clause 6.6 for making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer's RSV vaccine as that is the only vaccine used
- Clause 8.3 for potentially failing to approve (examine) responses to a media enquiry given that Sanofi declined to share their approved responses with us during intercompany dialogue
- Clause 5.1 for failing to maintain high standards
- Clause 2 for activities that undermine a national immunisation programme, risk public health and therefore bring discredit upon and reduce confidence in the pharmaceutical industry

The HSJ article (paid for article by Sanofi) highlights the same data from the Ireland neonatal immunisation programme and makes inappropriate and disparaging claims against the UK maternal RSV vaccination programme, suggesting the UK programme is inferior and leading to "worrying" outcomes. It raises concerns that there had not been a reduction in infant RSV hospitalisations during the winter in under-fives compared to the previous winter despite the UK vaccination programme. Similar to the Sunday Express article, it completely fails to explain that a maternal vaccination programme launching on 12 August 2024 in Scotland and 1 September 2024 in England and administered from 28 weeks gestation, is highly unlikely to show an impact in that timeframe on neonatal infections due to the time lag from pregnancy to birth. It is therefore scientifically inappropriate and misleading to compare the Irish programme with the UK programme at a timepoint that is significantly biased against the UK maternal vaccination programme.

During inter-company dialogue, Sanofi argued that the article is non-promotional because the individual products are not named. However, it is an accepted principle of the Code that content can be promotional if there is indirect reference to products. In this situation, the only product used in the Irish neonatal RSV immunisation programme is Sanofi's product nirsevimab, and the only product used in the UK maternal RSV vaccination programme is Pfizer's RSV vaccine. This article is therefore promotional, and it makes misleading and inappropriate comparisons between Sanofi's product and Pfizer's product.

The HSJ article is therefore in breach of:

- Clause 6.1 for making unbalanced, misleading and inaccurate claims and comparisons
- Clause 6.2 for making claims and comparisons that cannot be substantiated by scientific evidence
- Clause 6.6 for making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer's RSV vaccine as that is the only vaccine used
- Clause 8.1 for potentially failing to certify the article as promotional, given that Sanofi argued that it was a non-promotional article during inter-company dialogue
- Clause 5.1 for failing to maintain high standards
- Clause 2 for activities that undermine a national immunisation programme, risk public health and therefore bring discredit upon and reduce confidence in the pharmaceutical industry

The HSJ article was further amplified through several social media posts by [two named senior Sanofi employees]. These posts linked to the article and disseminated it to a much wider audience including the general public, further serving to undermine public confidence.

The social media posts are therefore in breach of:

- Clause 26.1 for promoting a POM to the public
- Clause 26.2 for making unbalanced and misleading information available to the public
- Clause 6.1 for making unbalanced, misleading and inaccurate claims and comparisons
- Clause 6.2 for making claims and comparisons that cannot be substantiated by scientific evidence
- Clause 6.6 for making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer's RSV vaccine as that is the only vaccine used
- Clause 8.1 for potentially failing to certify the social media posts as promotional, given that Sanofi argued that the linked article was non-promotional during inter-company dialogue
- Clause 5.1 for failing to maintain high standards
- Clause 2 for activities that undermine a national immunisation programme, risk public health and therefore bring discredit upon and reduce confidence in the pharmaceutical industry

Pfizer and Sanofi agreed on 1st August that inter-company dialogue had failed to resolve the issues in relation to the HSJ article and related social media posts.

In contrast to the scientifically flawed analysis presented by Sanofi, we have added 3 enclosures which demonstrate vaccine effectiveness for the Pfizer maternal vaccine against infant RSV associated hospitalisations. One enclosure is the final publication of the registrational phase 3 MATISSE trial, one is a publication of an analysis of the maternal RSV vaccination programme in England and Scotland, demonstrating vaccine effectiveness against infant RSV associated hospitalisations, the third is an analysis (currently in pre-print) by Public Health Scotland of the maternal RSV vaccination programme in Scotland demonstrating vaccine effectiveness against infant RSV associated hospitalisations.

The articles in the Observer, Sunday Express and HSJ are deeply concerning, scientifically flawed and serve to undermine public confidence in our national immunisation programme. In doing so they present a risk to public health. As such, Pfizer maintains that Sanofi's behaviour has failed to maintain high standards (in breach of Clause 5.1) and serves to bring discredit upon and reduce confidence in the pharmaceutical industry (in breach of Clause 2)."

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.6, 8.1, 8.3, 26.1 and 26.2 of the 2024 Code.

SANOFI'S RESPONSE

The response from Sanofi is reproduced below:

> "We refer to your letter dated 1st September 2025. Sanofi UK takes its obligation under the ABPI Code of Practice ("ABPI Code") very seriously, is concerned to have a complaint made about these articles. Sanofi UK would like to highlight that they feel that this formal complaint has come about because Pfizer had no intention of attempting to find a solution using inter company dialogue and this can be seen from their actions detailed below.
>
> **Sunday Express article**
>
> Sanofi UK received an unsolicited inquiry on the 6th of January 2025 from a journalist comprising of five specific questions about RSV immunisation programmes, real-world evidence, and the UK's approach to infant RSV protection. Our response to these questions addressed these queries factually and objectively. All the responses were reviewed and certified before being sent to the journalist in response to their questions.
>
> The 'sensationalist' and 'promotional' language allegedly used in the article was not derived from any communication sent to the journalist, as can be seen from our responses to the journalist question and therefore Sanofi UK cannot be held responsible for the language used within the article.
>
> Pfizer claim that Sanofi UK failed to fully explain the limitations of the maternal vaccination programme and its impact on the number of RSV cases at the time of the article was published. The information Sanofi UK supplied was in direct response to five specific and unsolicited questions from the journalist. None of these requested any information regarding the implementation of the maternal vaccine programme. Sanofi UK had no editorial input into the article and therefore cannot be held accountable for what information the journalist has chosen to include in their article other than that which we provided.
>
> The certification process for the responses to the journalists questions followed standard procedures for non-promotional scientific content. Please note that our medical signatory decided to make an additional revision, after the first version had been certified and sent to the journalist. The revisions where not material to the information used in the article and the change did not affect what was included in the article. The updated certified response was sent to the journalist. Sanofi UK has taken the opportunity to remind all signatories that they must ensure a thorough review of all materials before final approval given.
>
> Sanofi acknowledges that intercompany dialogue is the standard and preferred approach for resolving concerns between pharmaceutical companies. In this specific instance, our decision to only share the responses to the journalist directly with the PMCPA was made after careful consideration of the preceding months' interactions. The pattern of multiple simultaneous complaints, coupled with the nature and tone of previous intercompany exchanges, led us to conclude that traditional dialogue would not yield constructive outcomes.

Furthermore, we note that Pfizer attempted to include both the Sunday Express and HSJ articles as last minute additions to an intercompany dialogue meeting scheduled for an entirely different matter. They subsequently proceeded as inter-company dialogue had been completed and filed a formal complaint with the PMCPA. This then required [named senior Sanofi employee] to arrange a call with [the PMCPA] to ensure that the correct process was being followed.

This action suggested Pfizer were not acting in good faith when it comes to the ABPI Code complaint process.

HSJ Article

Sanofi maintains that the article's primary focus is on public health outcomes and healthcare system impacts, not specific products.

The article presents factual information about the burden of respiratory illnesses on paediatric services, healthcare capacity issues, economic impact, and international approaches to prevention. It discusses broad public health issues. The article provides a balanced view of the challenges faced in managing respiratory illnesses in children, particularly RSV, and presents factual data on different approaches to prevention. As data emerged of RSV-associated hospitalisations in the UK, legitimate questions could be asked of the immunisation approach, with expected results tempered by the program start date.

The data cited from Ireland and the UK represents documented public health outcomes from implemented national programmes. The comparison of national approaches to respiratory illness prevention reflects standard public health practice of evaluating different policy implementations. Case AUTH/3832/10/23 establishes how classes of medicines can be discussed in the public domain as the class of RSV prevention was discussed in this article.

The term 'worrying' in the context of this article specifically refers to hospitalization rates and healthcare system capacity, which we view as legitimate public health concerns, rather than any commentary on specific interventions. This aligns with the article's consistent focus on system-level outcomes and population health impacts.

Social Media

The article was certified as suitable for the public (enclosure 3 – additional elements in metadata to show intent) and so sharing on LinkedIn by Sanofi staff was appropriate. This position is consistent with the recent PMCPA ruling in Case AUTH/3832/10/23, which established that educational content discussing a class of medicines (without specific product promotion) falls within the exclusion from the definition of "promotion" in Clause 1.17 of the ABPI Code as "information relating to human health or diseases provided there is no direct or indirect reference to specific medicines." Therefore, sharing a non-promotional article on a social media platform is acceptable.

Sanofi UK would like to take this opportunity to reiterate, as vaccine business leaders and as members of the UK population, that our national immunisation programs are a

key element of public health and would not seek to undermine public confidence in it. Sanofi UK strongly supports public vaccination programs both globally and in the UK.

In summary, Sanofi UK does not believe that it has breached any of the ABPI Code clauses cited in Pfizer's complaint letter, for the reasons listed above and if you feel you need information, we are more than happy to provide it."

The PMCPA Panel asked Sanofi to provide a copy of the certificate for the HSJ article. The response from Sanofi is reproduced below:

"I am writing to provide you with an update regarding the review and approval process for the HSJ article (reference: MAT-XU-2500169).

The article was uploaded to PromoMats and underwent a comprehensive review as a non-promotional material intended for Healthcare Professionals (HCPs), ORDMs and members of the general public. The review process included examination by several ad hoc reviewers, Regulatory reviewers (as per our local/global requirements) and a Medical Signatory. The material was subsequently approved by the Medical Signatory on 7 February 2025.

Following initial approval by a medical signatory, the final form, incorporating the banner and additional elements from the HSJ website, was uploaded, by the material owner, for final form approval. Our investigation has revealed that the final form of the document was reviewed by the materials owner rather than by a medical signatory, which contravenes our Standard Operating Procedure and therefore we cannot provide a final form certificate for this material.

This deviation indicates that the materials owner has not followed our company SOP for this process. This has triggered an internal investigation to understand the root cause of this issue and actions will be taken to ensure that this doesn't happen again.

If you require further information regarding this issue, please contact me directly."

PANEL RULING

This case was in relation to an article in the Sunday Express, an article in the Health Service Journal and two social media posts by Sanofi about vaccination for the respiratory syncytial virus (RSV) which Pfizer alleged contained misleading claims, unsubstantiated comparisons, and disparagement.

Pfizer's RSV vaccine (that is administered to pregnant mothers) had been chosen for the UK's national immunisation programme. Sanofi's product, Beyfortus (nirsevimab), that is administered to neonates, infants and children up to 24 months if certain conditions are met,

had been chosen as the medicine for RSV in national immunisation programmes in other European countries, including Ireland.

Pfizer divided its complaint into the three materials:

1. The Sunday Express article
2. The Health Service Journal article
3. The LinkedIn posts

The Panel ruled on the complaint under these same three headings.

Material 1 – the Sunday Express article

This article ("Novel treatment set to save babies' lives from deadly virus") was published in the Sunday Express on 1 February 2025. As part of its response to the complaint, Sanofi provided the information it had given to the Sunday Express journalist on 9 January. The Panel accepted Sanofi's submission that the journalist's initial approach to Sanofi, and the questions they asked, were not solicited by Sanofi. This submission was supported by the journalist's email which indicated that they had been prompted to contact Sanofi by a press release from Ireland's Health Service Executive.

Given Sanofi had not provided Pfizer with the information it had provided to the journalist, Pfizer's complaint was about the Sunday Express article itself. However, the Panel took account of the established Code principle that complaints about independently published articles were judged on the material provided by a company to the journalist. The Panel therefore first considered the content of the article itself, and then the extent to which Sanofi should be held responsible for that content based on the information it had provided to the journalist.

The allegations

Pfizer alleged breaches of the following clauses of the Code:

1. Clause 6.1 – making unbalanced, misleading and inaccurate claims and comparisons
2. Clause 6.2 – making claims and comparisons that cannot be substantiated by scientific evidence
3. Clause 6.6 – making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer's RSV vaccine as that is the only vaccine used in the UK
4. Clause 26.1 – promoting a prescription only medicine to the public
5. Clause 26.2 – making unbalanced and misleading information available to the public
6. Clause 8.3 – failing to examine responses to a media enquiry
7. Clause 5.1 – failing to maintain high standards
8. Clause 2 – bringing discredit upon, and reducing confidence in, the pharmaceutical industry by undermining a national immunisation programme and risking public health

Sanofi's response

In summary, Sanofi's response was that:

- it provided unsolicited, factual answers to the journalist's questions,

- the language in the Sunday Express article was not from Sanofi,
- it had no editorial control over the article, and
- its responses were certified and non-promotional.

Extracts from the Sunday Express article

Given Pfizer's allegations, the Panel considered relevant extracts from the article written by the journalist to include the following:

- "A groundbreaking new treatment is set to save babies lives by protecting them against a deadly virus."

- "The one-off therapy, nirsevimab, is designed to protect against illness from respiratory syncytial virus (RSV) which can be deadly for infants."

- "The drug has been rolled out in Ireland where it is being hailed as a game-changer after official figures showed a stunning 94 percent drop in RSV-related hospitalisations among babies under one year old."

- "While Ireland and other European countries are using nirsevimab, the UK has opted for a maternal immunisation approach, prioritising vaccines given during pregnancy."

- "However, the latest UK Health Security Agency (UKHSA) data shows no significant reduction in RSV hospitalisations among children under five this winter compared to previous years. In fact, weekly hospital admissions peaked slightly higher in the 2024/25 season than in the previous RSV season."

- "Critics argue that relying on maternal immunisation alone leaves significant gaps in protection. Mothers must receive the vaccine at the right stage of pregnancy, and not all newborns receive the same level of immunity. In contrast, experts say, nirsevimab ensures direct and consistent protection for all treated infants."

Extracts from the information Sanofi provided to the journalist

The Panel then considered the information provided by Sanofi to the journalist to establish whether, on the balance of probabilities, the above extracts from the article were included in the article due to the information provided by Sanofi.

Sanofi's response to the journalist's five specific questions began with what was described as a summary followed by more detailed answers to each question. Although the Panel acknowledged that much of the detail was based on real-world data, the Panel was concerned about certain elements, including these extracts:

- "The Irish government's decision to choose a *direct protection* Respiratory Syncytial Virus (RSV) immunisation programme using nirsevimab, launched on 1st September 2024, has dramatically reduced RSV hospitalizations by **94%** in babies under one year old from 413 to 24 compared to the previous year, according to the Health Service Executive (HSE) 16th December 2024 press release" (emphasis as it appeared but footnotes to the source data removed)

- "The UK Government's decision to choose *indirect protection* with an RSV maternal immunisation programme does not yet appear to show any impact on the weekly hospitalisation data for RSV in the 0-5 year age group, according to the UK Health Security Agency (UKHSA) epidemiology surveillance, last updated on 3rd January 2025" (emphasis as it appeared but footnotes to the source data removed)

The Panel also bore in mind what appeared to be implied criticism of the Department of Health and Social Care (DHSC) decision to award the programme to the maternal immunisation programme, contrasting that decision with the decisions of Ireland, Spain and Germany. Further the summary discussed symptoms of RSV including severe disease and that RSV was the leading cause of infant mortality globally.

In response to the journalist's question – "How is the UK's new RSV vaccination programme working for infants and reducing hospitalisations?", Sanofi included the following in its answer:

- "In latest data published on 3 January 2025, weekly hospital admission rates in infants under 5 years of age are **tracking similar** for this 2024/25 RSV season compared to the 2023/24 RSV season" (emphasis as it appeared. A footnote was provided with a link to the gov.uk National flu and COVID-19 surveillance report: from 3 January 2025)

- "According to the latest available data published by the UKHSA, the peak of weekly hospital admission rates in infants under 5 years of age was higher for this 2024/25 RSV season (**42.24 per 100,000**) compared to last year, the 2023/24 RSV season (**41.5 per 100,000**)" (emphasis as it appeared. Footnotes were provided with links to the gov.uk National flu and COVID-19 surveillance report: 5 December 2024 and the UKHSA National influenza and COVID-19 surveillance report from 7 December 2023).

In response to the journalist's question – "Can you answer why the UK did not pick nirsevimab to protect infants from RSV?", Sanofi included the following in its answer:

- "The DHSC then launched a competitive tender process based on JCVI cost-effectiveness analyses. Following the competitive tender process, the DHSC chose to award the programme to the maternal immunisation option" (footnote provided with link to gov.uk press release announcing vaccination programme).

- "This decision is contrary to other European countries such as Ireland, Spain and Germany amongst others, who selected the monoclonal antibody option for their national immunisation programmes. The UK is currently the only high-income country to implement solely a maternal vaccination programme for the protection of infants and neonates from RSV" (footnotes provided with links to other countries' vaccination programmes).

Information, claims, comparisons and disparagement – Clause 6

In this section of the ruling, the Panel considered the allegations that fall under Clause 6 of the Code. The relevant sections relied up on by the Panel were:

> Clause 6.1: "Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the

evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine."

Clause 6.2: "Any information, claim or comparison must be capable of substantiation."

Clause 6.6: "The medicines, products and activities of other pharmaceutical companies must not be disparaged."

In deciding whether the material provided by Sanofi was acceptable in relation to Clause 6, the Panel bore in mind that the ultimate audience was the general public and the importance of caution and clarity when communicating with such an audience.

The Panel considered that the introductory bullet points in the summary set the tone for the whole document. The document began by using italics to emphasize that nirsevimab provides "*direct protection"* to babies whereas the maternal vaccine is "*indirect protection"* The Panel considered this emphasis implied to a lay audience that one form of immunisation was therefore more effective than the other. For reasons set out below, the Panel did not think that the data relied upon by Sanofi justified implying an RSV product for babies was more effective than a vaccine given to pregnant mothers.

The Panel also took account of the first introductory bullet point in the summary to Sanofi's response to the journalist, which stated that, in Ireland, nirsevimab "dramatically reduced" RSV hospitalizations of babies under one year old by 94% compared to the previous year.

The Panel particularly took into account the third introductory bullet point, reproduced above, which stated that the UK's "maternal immunisation programme does not yet appear to show any impact on the weekly hospitalisation data" (Panel's emphasis) and stated that this related to data updated on 3 January 2025. The Panel accepted Pfizer's submissions that the maternal vaccine programme began being administered to women who were 28 weeks pregnant in August 2024 (in Scotland) and September 2024 (in England). In the Panel's view, relying on hospitalisation data as at 3 January 2025 for infants 0-5 years old, was too soon to be able to draw any conclusions on the impact of the maternal vaccine in the UK that had been administered to pregnant women only four to five months previously. The first babies that may have been able to demonstrate the effectiveness of the maternal vaccine would likely only just have been born by 3 January 2025. In the Panel's view the position of the third bullet point (following the first and second bullet points in the summary, which referred in positive terms to the Irish, French and Spanish data) invited an unfavourable comparison between the UK data and the data for the Sanofi product. The Panel bore in mind Pfizer's submission that it was misleading to compare the Irish programme with the UK programme at a timepoint that is significantly biased against the UK maternal vaccination programme.

The Panel concluded it was misleading and unfair for Sanofi to compare:

- The impact of nirsevimab in Ireland by referring to the Irish hospitalisation data in infants under one year old from 1 September 2024 to 16 December 2024 compared to the previous year, with

- the impact of Pfizer's vaccine in the UK by referring to the UK hospitalisation data for RSV in the 0-5 age group from the 2023/24 season compared to the 2024/25 season (as at 3 January 2025) when the vaccine had only been administered to pregnant women from August (in Scotland) and September (in England) in 2024.

The Panel considered this to be a misleading comparison because it suggested Pfizer's vaccine was not having an impact, when that was not a conclusion that could be substantiated at that point in time. The misleading nature of the comparison was compounded by the answer to question 3 in the substantive part of Sanofi's response to the journalist which, in relation to UK data, stated that the peak of weekly hospital admission rates in infants under 5 years old was higher for the 2024/25 season compared to the 2023/24 season. In addition, this comparison did not provide sufficient information to enable recipients to form their own opinion of the therapeutic value of Pfizer's vaccine and nor was it capable of substantiation. For these reasons, the Panel ruled **breaches of Clause 6.1 and Clause 6.2**.

The Panel also considered Sanofi's answer to the journalist's question about why the UK chose a maternal vaccine. Part of Sanofi's answer stated: *"The UK is currently the only high-income country to implement solely a maternal vaccination programme".* The Panel considered the inference that the journalist was being asked to draw was that the UK was a clinical outlier within "high-income countries". In the Panel's view, the implication of this statement, coupled with the misleading comparison with the Irish data described above, cumulatively gave the impression that the maternal vaccine programme was not sufficient. That impression was further compounded by Sanofi's answer to question 3 in the substantive part of Sanofi's response to the journalist that emphasised (by using bold and underlining) that the 2024/25 season was worse than the 2023/24 season. The Panel viewed that as Sanofi not only suggesting that the Pfizer vaccine did not work, but also seeking to imply that it was potentially making the situation worse. The Panel did not consider that to be an accurate interpretation of the data and was therefore disparaging of Pfizer's vaccine. The Panel ruled a **breach of Clause 6.6**.

Promoting a prescription only medicine to the public – Clause 26.1
Making unbalanced and misleading information available to the public – Clause 26.2

Clause 26.1 stated:

> "Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers."

Clause 26.2 stated:

> "Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.
>
> 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 took account of the MHRA Blue Guide which stated:

> "Particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programmes, and which could result in the promotion of prescription only medicines to the general public."

For the reasons set out above in relation to the breaches under Clause 6, the Panel did not think that Sanofi had taken particular care in this case, and that the promotional nature of its briefing to the journalist had resulted in the promotion of a prescription only medicine to the public. The Panel therefore ruled a **breach of Clause 26.1**.

In its consideration of Clause 26.2, the Panel also took account of Sanofi's use of the superlative adverb "dramatically", when referring to the 94% reduction in hospitalisations in Ireland. The Panel did not consider this to be consistent with the requirements of Clause 26.2 which required information made available to the public (either directly or indirectly) to be factual and presented in a balanced way. In the Panel's view, Sanofi's choice of language would have likely encouraged the journalist to describe this as a "stunning 94 percent drop" in their article.

The Panel also considered Sanofi's response to the journalist to not be balanced or factual (in relation to its misrepresentation of the UK position compared with Ireland) by basing it on incomplete UK data and that the Panel's reasoning in relation to its ruling of a breach of Clause 6.1 and Clause 6.2 applied equally here. The comparison between the two immunisation programmes was not fair and the Panel concluded that this amounted to presenting information about nirsevimab to the public in a way that was not balanced. The Panel therefore ruled a **breach of Clause 26.2**.

Examination of a response to a media enquiry – Clause 8.3

Sanofi provided the Panel with a certificate showing that its original and amended response to the journalist had been certified. Sanofi had chosen to go beyond the requirements of Clause 8.3 by certifying its response to a media enquiry, when only examination was required. The Panel therefore ruled **no breach of Clause 8.3**.

High standards – Clause 5.1

The Panel considered the overall importance of companies providing accurate information and ensuring that comparisons are based on an up-to-date evaluation of all the evidence. That was especially important for information that is being provided to a mainstream media journalist for ultimate consumption by the public. The Panel took account of the extent to which Sanofi's comparison was misleading, in addition to how the disparagement of Pfizer's vaccine was based on that misleading comparison. The Panel ruled a **breach of Clause 5.1**.

Discrediting the industry – Clause 2

The Panel considered, on the balance of probabilities, that Sanofi would have known that providing this sort of misleading comparison to a mainstream media journalist, was very likely to result in an article designed to catch the attention of parents and expectant parents. Given the broad readership of the Sunday Express, and the understandable heightened concerns that new and expectant parents have for their babies, it was particularly important that any comparisons of this nature were accurate and substantiable.

The Panel recognised the importance of the role vaccination programmes play in reducing and eliminating infectious diseases and the particular importance of maintaining public confidence in immunisation efforts.

The Panel considered that the likely effect of the misleading comparison was to undermine the UK Government's vaccine programme by stating that it had not had "any impact" (or even implying it was making hospitalisations rise compared to the previous winter). Further, in the Panel's view, Sanofi's response to the journalist was critical of DHSC's decision to select the Pfizer vaccine.

In the national context of a declining uptake of vaccines, the Panel also viewed this as a potential public health concern. Prejudicing public health is one of the examples of activities likely to be in breach of Clause 2, as set out in the supplementary information to that clause.

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

Material 2 – the Health Service Journal article

The second material that Pfizer complained about was an article in the Health Service Journal (HSJ), that was written by a Sanofi senior leader. Their job title was not provided. The article stated that it was "Funded and produced by Sanofi". This article was dated 13 February 2025; shortly after the Sunday Express article that was published on 1 February 2025.

The title of the HSJ article was "Helping prevent paediatric winter pressures: Spotlight on evaluating the UK's immunisation programme".

The allegations

Pfizer alleged breaches of the following clauses of the Code:

1. Clause 6.1 – making unbalanced, misleading and inaccurate claims and comparisons
2. Clause 6.2 – making claims and comparisons that cannot be substantiated by scientific evidence
3. Clause 6.6 – making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer's RSV vaccine as that is the only vaccine used in the UK
4. Clause 8.1 – failing to certify the article as promotional
5. Clause 5.1 – failing to maintain high standards
6. Clause 2 – bringing discredit upon, and reducing confidence in, the pharmaceutical industry by undermining a national immunisation programme and risking public health

Given the nature of Pfizer's allegations, the Panel considered the relevant extracts to be from the second section of the article headed "Prioritising rapid adoption of innovative, preventative options".

The article described the same data that was provided to the Sunday Express journalist, showing a 94% reduction in hospitalisations in Ireland in the 2024/25 season compared to the 2023/24 season. It then stated:

- "As we monitor the impact the UK's programme is having on the burden of RSV on infants, data so far suggests RSV testing positivity in those aged zero to four years and hospital admission rates for those under five years old are roughly the same this year as the 2023-24 winter season, which I believe is worrying."

- "With winter ending soon, we'll have a more complete picture of the performance of our national vaccination/immunisation programmes for the 2024-25 season. However, given the peaks of several respiratory illnesses have likely already passed, I believe we can start asking questions now."

- "What impact have the UK's vaccination programmes had on reducing infant hospitalisations for respiratory infections?"

- "How do outcomes, particularly for children in the UK, compare to those in other high-income countries?"

- "In my opinion, perhaps the biggest question of them all might be: will the UK government take any steps that are necessary in the future to be a world leader in helping to give infants the best start in life, or celebrate achieving low targets?"

Information, claims, comparisons and disparagement – Clause 6

The Panel relied on the same extracts of Clauses 6.1, 6.2 and 6.6 as referred to in relation to the Sunday Express article allegations above.

The Panel considered that the HSJ article made the same misleading comparison in relation to the 94% figure from Ireland (the hospitalisation reduction from the 2023/24 season to the 2024/25 season), compared to the UK data. The article stated that the UK data demonstrated hospitalisation rates for those under five years old were "roughly the same this year as the 2023-24 winter season, which I believe is worrying".

The reference for this statement was "GOV.UK. National flu and COVID-19 surveillance reports: 2024 to 2025 season". There was no specific date given for the point at which the author was asserting the hospitalisation rates were roughly the same. Nevertheless, the Panel reached the same conclusion as with the Sunday Express article. Even taking Sanofi's case at its highest (i.e. that the article was based on data in early February in advance of the article being published in the HSJ on 13 February), the Panel still considered that to be too early a point in time to be able to draw accurate conclusions from the impact of a maternal vaccine on those in the age range 0-5 years old, when the vaccine had begun being administered to pregnant women approximately five months earlier. The article implied that the comparison between the Irish and UK hospitalisation data was valid, stating that given the peaks of several respiratory illnesses had likely already passed 'I believe we can start asking questions now.' The Panel therefore considered this to be a misleading comparison, and one that could not be substantiated by the data. The Panel ruled **breaches of Clause 6.1 and Clause 6.2**.

The Panel also took account of the author relying on the above misleading comparison to state that the situation in the UK was "worrying" and then implying that the UK Government was not giving infants the best start in life and was choosing to "celebrate achieving low targets". This implication was compounded by the discussion in the introductory section of the article about

the incidence of severe RSV disease in infants and their vulnerability to serious infections and hospitalisation. The Panel considered this to be clearly disparaging of the UK RSV vaccination programme and, by association, Pfizer's medicine. On that basis, the Panel ruled a **breach of Clause 6.6**.

Failure to certify the article as promotional – Clause 8.1

The Panel considered that it had to decide whether the article published in the HSJ was promotional and whether the article went beyond a discussion of classes of medicine or public health as implied by Sanofi. The Panel acknowledged that the article did not name the products at issue but considered that it invited health professionals and other relevant decision makers to directly and unfavourably compare the vaccine used in the UK with the medicine used in Ireland. The Panel bore in mind its comments above about the comparison and the requirements of Clause 6. Noting the broad definition of promotion at Clause 1.17 and the nature of HSJ's readership the Panel considered that the article was promotional and required certification.

In its further response to the Panel, Sanofi conceded that it had failed to comply with the requirement to certify the final form of the HSJ article. The Panel therefore ruled a **breach of Clause 8.1**.

High standards - Clause 5.1

As with the Sunday Express article, the Panel considered the overall importance of companies producing accurate information and ensuring that comparisons are based on an up-to-date evaluation of all the evidence. Although the Panel acknowledged that the HSJ is a subscription publication and therefore not freely available to all, its readership was much broader than health professionals and included other relevant decision makers. The Panel took account of the extent to which the comparison was misleading and how the disparagement of Pfizer's vaccine was based on that misleading comparison. The Panel also relied upon the governance failings involved in Sanofi's admission that it had failed to comply with its own SOP and not certified the final form of the HSJ article. The Panel considered that there had been a failure to maintain high standards and ruled a **breach of Clause 5.1**.

Discrediting the industry – Clause 2

The Panel was concerned that the impact of this article could be significant, given the wide readership of health professionals, other relevant decision makers and those working in, or with an interest in, the health sector. Sanofi should have been aware that providing this sort of misleading comparison to the UK health sector at large, could result in the commissioning decisions of DHSC being discredited, particularly as the impact of the UK programme was described as 'worrying'. Given the potential direct and indirect interaction with the public about vaccination by the HSJ readership and their potential impact on and management of local vaccine programmes the Panel considered it was particularly important that any comment on the effectiveness of the UK immunisation programmes directed at this audience complied with the Code.

The Panel believed that the likely effect of the misleading comparison in this case was to undermine the UK Government's vaccine programme by (a) implying the Pfizer vaccine has not shown sufficient effect and (b) stating that it had created a situation that was "worrying". In

addition, the senior leader encouraged the readership of the HSJ to “start asking questions now” and implied that the UK Government was not currently giving infants the best start in life. All the above, at the time the article was published, was based on a misleading comparison underpinned by UK data that was not yet sufficiently complete for such comparisons to be made.

As with the Sunday Express article, the Panel also viewed this as a potential public health concern in the national context of a declining uptake of vaccines.

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

Material 3 – the LinkedIn posts

The third part of Pfizer’s complaint related to two LinkedIn posts that linked to the HSJ article. The first was a post by the Sanofi senior leader who had authored the HSJ article. The Panel noted that Pfizer’s allegation was that the URL link to the HSJ article, within the post, would have amplified the article by disseminating it to a wider audience on LinkedIn.

The second LinkedIn post was by a Sanofi employee who had reposted the senior leader’s post and added “Some excellent questions raised”.

The Panel relied on the overriding objective in the PMCPA Constitution and Procedure and considered it proportionate to treat these two related posts as one material for the purposes of this case. That is also consistent with the way in which Pfizer complained about them. The ruling therefore refers to them collectively as “the posts”. Pfizer made the following allegations about the posts:

1. Clause 6.1 – making unbalanced, misleading and inaccurate claims and comparisons
2. Clause 6.2 – making claims and comparisons that cannot be substantiated by scientific evidence
3. Clause 6.6 – making disparaging comments about the UK maternal RSV national immunisation programme and by extension Pfizer’s RSV vaccine as that is the only vaccine used in the UK
4. Clause 26.1 – promoting a prescription only medicine to the public
5. Clause 26.2 – making unbalanced and misleading information available to the public
6. Clause 8.1 – failing to certify the posts as promotional
7. Clause 5.1 – failing to maintain high standards
8. Clause 2 – bringing discredit upon, and reducing confidence in, the pharmaceutical industry by undermining a national immunisation programme and risking public health

It is an established principle from the PMCPA’s social media guidance and case precedent that links provided in social media posts are considered part of the post. In this case, that meant that the posts included the HSJ article.

The Panel considered that the above **breaches of Clause 6.1, Clause 6.2, Clause 6.6, Clause 5.1 and Clause 2** in relation to the HSJ article applied equally to the LinkedIn posts.

The Panel then considered the remaining alleged clause breaches for the posts in turn.

Clause 26.1 – promoting a prescription only medicine to the public

The Panel acknowledged that neither the posts, nor the HSJ article, referred to nirsevimab by name. However, it is an established principle, as set out in PMCPA case precedent and a PMCPA Q&A, that a medicine can be promoted without its name being mentioned. The Panel relied on the following factors to conclude that the dissemination of the article via the LinkedIn posts was advertising a prescription only medicine to the public:

1. Although the article purported to be about respiratory illnesses in general, the overall emphasis was on RSV as the case study. There were repeated references to this as the indication.

2. The misleading comparison between the Irish data and the UK data presented the Irish immunisation programme (which used nirsevimab, for which Sanofi had the marketing authorisation), in a very positive light.

3. Overall the article was peppered with promotional language, such as the Irish example resulting in a "significant reduction" whereas the UK situation was "worrying".

Given the promotional nature of the article in relation to nirsevimab, and that it had been disseminated by a Sanofi senior leader on LinkedIn, the Panel ruled that a prescription only medicine had been promoted to the public and ruled a **breach of Clause 26.1**.

Clause 26.2 – making unbalanced and misleading information available to the public

For the reasons given above about the article's misleading comparison of the data from Ireland and the UK, the Panel concluded that misleading information had been made available to the public via the posts. The Panel ruled a **breach of Clause 26.2**.

Clause 8.1 – failing to certify the posts as promotional

Sanofi initially submitted that it had certified the article as suitable for the public and therefore believed that sharing the post on LinkedIn was appropriate. The metadata indicated that the intended audience for the article was the general public. Sanofi subsequently conceded that the final form of the HSJ article had not been approved. Given the Panel's conclusion above in relation to Material 2 (that the HSJ article itself was promotional), the Panel similarly concluded that the posts which contained additional text linking to that promotional HSJ article should also have been certified. There was no evidence before the Panel that the posts which disseminated the HSJ article had been certified; they had to be certified as standalone items and could not

rely on a reference to public dissemination in the metadata of the HSJ article. The Panel ruled a **breach of Clause 8.1**.

Report to the Code of Practice Appeal Board

Due to the cumulative and serious nature of the breaches of the Code ruled in this case, the Panel decided to report Sanofi to the Code of Practice Appeal Board (in accordance with Paragraph 10.2 of the PMCPA Constitution and Procedure) for the Appeal Board to consider in relation to Paragraph 13.4.

The key reasons for the Panel's decision to report Sanofi are largely derived from the Panel's reasoning in its Clause 5.1 and Clause 2 breach rulings above. In short, these are:

1. Since the Covid-19 pandemic, there has been a degree of public scepticism and debate about vaccine efficacy. It is therefore critical that material about vaccine efficacy (particularly in relation to public health vaccination campaigns) is accurate. Misleading claims and comparisons can undermine the public's trust in vaccination campaigns, leading to fewer people being vaccinated and, ultimately, creating public health concerns.

2. This was not an isolated incident, but part of a broader campaign across different media outlets.

3. The broad readership of the mainstream publications:

    a. new and expectant parents, and the general public (Sunday Express),
    b. health professionals, decision makers, and those influencing immunisation programmes (HSJ), and
    c. the broad reach of social media (LinkedIn).

4. The claims/comparisons (and the disparagement of Pfizer's medicine and the UK Government's vaccination programme) were premised on a very misleading interpretation of the data and were not substantiable.

5. It is important that the Panel can rely upon a company's response. Sanofi did not appear to have done its due diligence before submitting its initial response because:

    a. it implied that the reference to public dissemination in the 'approval' of the HSJ article also covered the LinkedIn posts, rather than an awareness that these were different materials requiring separate approval, and

    b. the true picture in relation to certification only became apparent after further enquiries from the Panel.

APPEAL BOARD'S CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board took account of the Panel's comments and rulings of breaches of the Code (including the three rulings of a breach of Clause 2) and the reasons for its decision to report Sanofi to the Appeal Board.

The Appeal Board heard submissions from Sanofi representatives who confirmed that Sanofi took full responsibility for the failings that had led to the breaches in this case and recognised the impact of its actions. The representatives submitted that the issue was limited to one business unit within the company and the conduct in question lasted for a short period of time. In relation to corrective action, the representatives explained that there had been a significant change in leadership personnel since the time of the complaint, and a range of governance and process improvements had been implemented to avoid similar breaches occurring in future. Furthermore, an audit, to be conducted by a third party, was scheduled to begin on 1 June and be completed by the end of July 2026.

Having considered the Panel ruling, and Sanofi's submissions at this hearing, the Appeal Board was concerned about the seriousness of the breaches in this case and Sanofi's conduct in relation to it. The Appeal Board considered the range of options available to it by way of further sanctions under Paragraph 13.4 of the Constitution and Procedure. Firstly, the Appeal Board decided that the matter was sufficiently serious, such that Sanofi should be publicly reprimanded, for the reasons set out in the public reprimand below.

Secondly, the Appeal Board discussed whether to require a PMCPA audit but decided to require a senior representative from Sanofi to attend the Appeal Board in October 2026. At that meeting, the Appeal Board expected Sanofi to provide a copy of the third-party audit report and to provide details of the actions it has taken, and is taking, as a result of that audit. The Appeal Board would expect the third-party audit to assess, as a minimum, Sanofi's culture, compliance programme, Code adherence and implementation of SOPs. The Appeal Board reserved the decision regarding the application of additional sanctions until consideration of this information.

The Appeal Board agreed the following public reprimand:

> "Sanofi has been publicly reprimanded by the Code of Practice Appeal Board for its very serious breaches of the ABPI Code, related to disparaging claims and comparisons made about the UK's RSV vaccination programme for infants, which were based on a highly misleading interpretation of data.
>
> The Appeal Board considered the findings from Case/0689/08/25, which related to a complaint about articles in the Sunday Express and the Health Service Journal, and two related social media posts. The Panel had ruled breaches of Clauses 2(x3), 5.1(x3), 6.1(x3), 6.2(x3), 6.6(x3), 8.1(x2), 26.1(x2) and 26.2(x2) of the Code.
>
> The Appeal Board also took account of the related Case/0518/03/25, in which the Panel had ruled breaches of Clauses 2, 5.1, 6.1(x2), 6.2(x2), 6.6, 26.1, 26.2(x3).
>
> The Appeal Board bore in mind that the Panel decided to report Sanofi to the Appeal Board because of the cumulative and serious nature of the breaches of the Code. The Panel gave the following key reasons for its decision to report Sanofi to the Appeal Board in relation to the significant multiple breaches:
>
> 1. Since the Covid-19 pandemic there has been a degree of public scepticism and debate about vaccine efficacy. It is therefore critical that material about vaccine efficacy (particularly in relation to public health vaccination campaigns) is accurate. Misleading claims and comparisons can undermine the public's trust in

vaccination campaigns, leading to fewer people being vaccinated and, ultimately, creating public health concerns.

2. This was not an isolated incident but part of a broader campaign across different media outlets.

3. The broad readership of the mainstream publications, namely:
    a. new and expectant parents and the general public (Sunday Express);
    b. health professionals, decision makers and those influencing immunisation programmes (HSJ), and
    c. the broad reach of social media (LinkedIn).

4. The claims/comparisons (and the disparagement of Pfizer's medicine and the UK Government's vaccination programme) were premised on a very misleading interpretation of the data and were not substantiable.

5. It is important that the Panel can rely upon a company's response. Sanofi did not appear to have done its due diligence before submitting its initial response because:

    a. it implied that the reference to public dissemination in the 'approval' of the HSJ article also covered the LinkedIn posts, rather than an awareness that these were different materials requiring separate approval, and

    b. the true picture in relation to certification only became apparent after further enquiries from the Panel.

Further to this, the Panel also raised concerns in the report to the Appeal Board about how Sanofi had behaved both during intercompany dialogue (ICD) stage and once the complaint had been made to the PMCPA. The Panel noted that Sanofi had not provided full information to Pfizer during the ICD.

At the May 2026 Appeal Board meeting, representatives of Sanofi accepted:

1. the serious nature of the breaches,

2. the impact the company's actions had or were likely to have on the wider vaccination programme, and

3. that there were cultural, compliance and governance issues within Sanofi at the time.

The Appeal Board wholeheartedly agreed with the concerns raised by the Panel about the nature and seriousness of the breaches. The use of thoroughly misleading data, on multiple occasions, to disparage a competitor's medicine (and, by association, a critically important national vaccination programme) was indicative of a complete absence of appropriate compliance checks and balances and a culture within Sanofi that significantly brought the pharmaceutical industry into disrepute.

The Appeal Board was also extremely concerned by the manner in which Sanofi had engaged with Pfizer in the ICD, and with the PMCPA in relation to the complaint. The Appeal Board considered that such conduct undermined effective self-regulation, which required frankness, transparency and proper engagement at all stages of the process.

For these reasons, the Appeal Board had no hesitation in concluding that Sanofi should be publicly reprimanded as an additional sanction.

The Appeal Board also considered whether to require an audit of Sanofi's procedures in relation to the Code, to be carried out by the PMCPA. On hearing from the representatives of Sanofi, all of whom had leadership roles, and all bar one having come to their role after the complaints were made, the Appeal Board took account of Sanofi's submission that the new leadership was delivering a change of culture and governance.

Sanofi informed the Appeal Board that an audit by a third party was imminent, in which all procedures in Sanofi would be 'pressure tested'.

Rather than require a PMCPA audit at this stage, the Appeal Board decided to require a senior representative from Sanofi to attend the Appeal Board in October 2026. At that meeting, the Appeal Board expected Sanofi to provide a copy of the third-party audit report and to provide details of the actions it has taken, and is taking, as a result of that audit. The Appeal Board would expect the third-party audit to assess, as a minimum, Sanofi's culture, compliance programme, Code adherence and implementation of SOPs. The Appeal Board reserved the decision regarding the application of additional sanctions until consideration of this information."

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