CASE/0688/08/25

PFIZER v SANOFI

Allegations regarding a press release

CASE SUMMARY

This case was in relation to a press release issued by Sanofi's global headquarters in Paris. The press release related to Sanofi's REACH study which compared the UK with Spain in relation to RSV-related infant hospitalisations.

In the UK, the national immunisation programme used Pfizer's maternal RSV vaccine, Abrysvo (RSVpreF). In Spain, the national immunisation programme used Sanofi's Beyfortus (nirsevimab). The press release referred to a 69% reduction in RSV-related infant hospitalisations in Spain, versus a 26.7% reduction in the UK.

Pfizer alleged that the comparison was scientifically flawed and biased against the UK programme because the period during which the hospitalisation data had been measured included many infants who may not have benefited from the UK's maternal vaccination programme. Sanofi's response was that the press release fell outside the scope of the ABPI Code as a global communication not targeted at a UK audience.

The outcome under the 2024 Code was:

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 comparison and referring to relative risk without absolute risk**
Breach of Clause 6.2	**Making a claim that was incapable of substantiation**
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	**Providing inaccurate and unbalanced information to the public**

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

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 Limited.

COMPLAINT

The complaint wording is reproduced below:

> "Following our complaint earlier this year about an article in the Observer featuring an interview with Sanofi's [global senior leader], and in addition to our second complaint regarding articles in the Sunday Express and HSJ, Pfizer is disappointed to have to initiate a third complaint regarding a press release issued by Sanofi's global headquarters in Paris following the presentation of their REACH study at the European Society for Paediatric Infectious Disease (ESPID) congress on 29th May 2025.
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> The REACH study was a non-randomised, retrospective analysis which sought to evaluate changes in the number of RSV related infant hospitalizations in the UK and Spain before and after introduction of two different RSV immunization strategies. These distinctly different strategies involve passively immunizing infants after birth with a monoclonal antibody (Sanofi's Beyfortus (nirsevimab) in Spain) compared with immunizing pregnant women to provide protection to infants from birth (Pfizer's maternal RSV Vaccine in the UK).
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> Pfizer disagrees with Sanofi's view that the press release is not in scope of the ABPI Code of Practice. The press release highlighted the use of Pfizer's RSV vaccine in the UK compared with Sanofi's Beyfortus product in Spain and their associated clinical outcomes. As explained below, the comparison is scientifically flawed and misleading and is promotional in nature suggesting that the UK programme using Pfizer's RSV vaccine is inferior to the Beyfortus programme in Spain. As the press release was issued by an affiliate of Sanofi UK and makes specific and disparaging reference to use of Pfizer's maternal RSV vaccine in the UK vaccination programme, Pfizer believes that the press release meets the criteria of Clause 1.2 of the Code. Therefore, information presented by Sanofi in the press release about the Pfizer and Sanofi products must meet all requirements and standards set out in the Code. Sanofi did not agree with this position, and we therefore concluded on 1st August that inter-company dialogue had failed to resolve the issues.
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> To explain the issues in more detail, in order to legitimately evaluate the population-level impact of an immunisation programme, it is essential that the population included in the study be eligible to benefit from the programme. While this fundamental concept was incorporated into the design of the impact evaluation in Spain, it was not properly applied to the evaluation in the UK. To properly evaluate the impact of a maternal vaccination programme, the study must account for (1) timing of the programme introduction, (2) expected timing of births based on the gestational age window of the programme and (3) expected attained age of infants eligible for protection within the study period under consideration.
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> In the UK, the maternal RSV vaccination programme was introduced in Scotland on 12th August 2024 and in England on 1st September 2024 for all pregnant women who were at 28 weeks of gestational age or higher. Given the timing of the RSV programme introduction and the eligible pregnancies, it was misleading in the REACH analysis to evaluate population-level impact in the UK among infants beyond 6 months of age by 31st March 2025 (the time period analysed) because the oldest infant who could have

benefitted from the programme would only just be reaching 6 months of age by the very end of the study period. In addition, infants who were hospitalised earlier in the study period (for example a 6-month-old hospitalized in November 2024) could not possibly have been born to a vaccinated mother, since they were born before RSV vaccine was available. Since many of the infants included in the REACH study from the UK would not have been eligible to benefit from the RSV programme, the impact would be biased downward. Comparing to a cohort of infants in Spain, all of whom received Beyfortus after birth, is therefore inappropriate and scientifically flawed.

The Sanofi press release about the REACH analysis makes misleading, inaccurate and unsubstantiable promotional claims about the Beyfortus programme in Spain compared to the maternal RSV vaccination programme in the UK. There is no transparency in the press release about the serious limitations of the analysis conducted and the misleading nature of the comparison. In addition, the press release quotes relative risk reductions without absolute risk reductions. As a result of this flawed analysis, the press release disparages the UK vaccination programme and the Pfizer maternal RSV vaccine.

Pfizer therefore believes the press release is in breach of:

- Clause 26.1 for promoting a POM (Beyfortus) 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 national immunisation programme and the use of Pfizer's RSV vaccine in the programme
- Clause 8.3 for failing to examine a press release that is in scope of the Code
- 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

Presenting scientifically inaccurate and misleading information can have a negative impact upon public health and in this particular case Sanofi's actions are egregious because they undermine the collective efforts of the RSV medical and scientific community to protect infants from this serious respiratory disease. 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).

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 [the final publication of the registrational phase 3 MATISSE trial, a publication of an analysis of the maternal RSV vaccination programme in England and Scotland, demonstrating vaccine effectiveness against infant RSV associated hospitalisations, and 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.]

Given the misleading nature of the REACH analysis, Pfizer requested that Sanofi immediately cease dissemination of the REACH study via digital channels, media and social media and refrain from promotion of the REACH study with UK healthcare professionals and other relevant decision makers. Sanofi did not agree to this request, and we therefore concluded that intercompany dialogue had not resolved the issues.

This is the third in a series of complaints demonstrating a concerted effort by Sanofi to mislead healthcare professionals and the public about the Pfizer maternal RSV vaccine, with inappropriate and scientifically flawed claims that it is inferior to Sanofi's Beyfortus product. Sanofi's campaign of activities serves to undermine public confidence in our national immunisation programme, which is there to protect infants against a serious respiratory disease which carries a high morbidity and mortality. During inter-company dialogue, Sanofi was unable to confirm that similar activities would not continue in the future. Given the seriousness of the situation, Pfizer respectfully requests that the PMCPA expedites the ruling for these three complaints."

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.6, 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 in which you have shared with us a complaint from Pfizer regarding allegations made about a global press release.

Sanofi UK takes its obligation under the ABPI Code of Practice ("ABPI Code") very seriously, is concerned to have a complaint made about this issue.

Sanofi UK rejects the allegations of any breach of the ABPI Code in respect of this press release and we will set out our reasons for that in the following paragraphs.

In essence, Sanofi UK does not believe that this press release comes under the remit of the ABPI Code. The REACH study press release was a global communication issued from our global headquarters in Paris and intended for an international audience, concerning the outputs of a global clinical trial. It was not targeted to, or intended for, a UK audience and Sanofi UK does not reference our product's availability in the UK. If these types of press releases are to be judged as coming under the remit of the ABPI Code, this would enable the ABPI Code to have extraterritorial reach and would place disproportionate constraints on global pharmaceutical companies not headquartered in the UK.

Background to the press release

It is common practice for pharmaceutical companies to issue a press release when the read out from a clinical trial is made public. The context in which the press release was issued, and its content were entirely consistent with a non-promotional purpose.

Sanofi UK was made aware of the existence of the press release, about a week before its use at the ESPID conference. It had been through Global review and approval, as do all press releases and once Sanofi UK was aware of the press release, then we took the following specific measures to limit exposure of a global press release to UK audiences and in fact, to the remit of the ABPI Code itself:

1. International audience focus: We verified that the press release was explicitly designed as a global communication for international news media, that no one from the UK had been involved in its creation and that it was not specifically targeted at UK healthcare professionals or the UK public.

2. No UK-specific media targeting: The press release was globally issued through news wire services. No UK-specific media were targeted for this press release by either global or local communications teams.

3. No proactive localisation: The press release was not adapted or localised for the UK audience. It remained in its global format without UK-specific localisation or contact information.

4. No dissemination through UK social media: We did not disseminate the press release or study results through UK social media channels, nor did anyone in the UK organisation engage with or amplify global posts. A communication was sent to all relevant employees to refrain from engaging with this press release on any social media outlet.

5. Financial Times coverage: We note Pfizer's concern about the re-post of the press release by the Financial Times. This was a direct syndication of the press release directly from the newswire – the source cited was Globe Newswire, which is a large and wide-reaching US-based newswire. Sanofi did not send this release directly to the Financial Times. To reiterate no UK specific news vendors were proactively approached or targeted.

Regarding the broader concerns about global communications in today's interconnected world, we acknowledge that it is impossible to completely prevent UK audiences from accessing information that is published globally. Sanofi UK believes it would be proportionally unfair for the ABPI Code to apply extraterritorially, unless there was clear evidence of targeting of a UK audience, which this press release does not do. We believe we have taken all reasonable measures to limit UK exposure and relevance, which we have demonstrated above. Given the present socioeconomic landscape, it is crucial for the UK to maintain and enhance its competitive pharmaceutical landscape by fostering an environment that continues to attract international business investment and operations.

If the PMCPA feel that the press release does come under the remit of the ABPI Code, Sanofi UK would be happy to provide further information as to why we do not feel it breaches any of the other clauses stated within their complaint letter.

Sanofi UK strongly supports public vaccination programs globally and in the UK. The REACH study contributes to the scientific understanding of different RSV prevention strategies. Scientific discourse and comparative research are essential for advancing

public health, and presenting study findings does not constitute disparagement of any national program.

Additional Points

In regards to Pfizer's statement of "Pfizer requested that Sanofi immediately cease dissemination of the REACH study via digital channels, media and social media and refrain from promotion of the REACH study with UK healthcare professionals and other relevant decision makers" and that this was the reason that inter company dialogue was ceased, is factually incorrect. As made clear in our initial response to Pfizer the press release was never intended for use in the UK and has never been used promotionally with HCPs or ORDMs in the UK. We cannot agree with Pfizer's demands due to the fact we have not undertaken any of the activities they are asking us to stop.

Sanofi UK believes that Pfizer is not using the PMCPA complaints process in the spirit in which it is meant and believes, that due to the number of intercompany dialogue requests we have received and how they have failed to reach any meaningful outcomes as part of that process, that this is part of their aggressive strategy towards Sanofi UK to cause disruption.

In summary, Sanofi UK therefore denies breaching of any clauses alleged by Pfizer in its complaint due to the fact that we do not believe that the press release for the REACH study falls under the scope of the ABPI Code, as a solely global activity which has not be directed at a UK audience."

FURTHER INFORMATION REQUESTED FROM SANOFI BY THE CASE PREPARATION MANAGER

The case preparation manager wrote to Sanofi on 22 January 2026 to say that this matter would be referred to the Panel. They invited Sanofi to provide any additional information that it would like the Panel to consider in relation to the clauses raised by Pfizer, if the Panel was to find that the matter was within scope of the Code. The further response from Sanofi is reproduced below:

"We refer to your letter dated 22nd January 2026 requesting additional information that Sanofi UK would like the panel to consider as part of our response to Pfizer's allegations, as set out in your letter dated 1st September 2025.

Further to our letter dated 23rd September 2025, Sanofi UK denies the breaches of the ABPI Code alleged by Pfizer and it is our submission that the subject matter of this complaint does not fall within the scope of the ABPI Code.

Background

There are no approved RSV vaccines for infants. RSV in infants can be prevented through either direct immunisation with a monoclonal antibody administered to the infant at birth, or else through vaccination of the pregnant mother for transplacental passive immunisation of the baby in-utero. Sanofi manufactures one such monoclonal antibody (Beyfortus, nirsevimab) and Pfizer manufactures a maternal vaccine Abrysvo (RSVpreF). Across the world, different health systems have adopted different strategies

to prevent infant RSV. The UK is an example of one of the countries that has implemented a maternal vaccination-only strategy. Several European countries, including Spain, implemented a monoclonal antibody-only strategy. Other countries have adopted programs comprising a mixture of both approaches (i.e. maternal vaccination and monoclonal antibody).

Immunisations be measured at the product level and at the population level. Pivotal clinical trials for licensure generated data on the efficacy of the monoclonal antibody or the maternal vaccine in preventing RSV hospitalization in trial participants who received the product. In contrast, at a population level, the overall public health impact of the RSV prevention program can be assessed by measuring overall hospitalization for RSV.

The public health impact of an immunisation strategy extends beyond the efficacy of individual products. It depends on the successful implementation of the entire program, including vaccine coverage rates, which are influenced by multiple factors, including public acceptability, access to services and program infrastructure. Sanofi's observational, retrospective REACH study built on the existing product efficacy data generated for licensure by measuring the overall real-world public health impact of the chosen immunisation strategies in Spain and in the UK.

The REACH study was presented at the European Society for Paediatric Infectious Diseases conference on 29th of May 2025. Sanofi considered the results of its REACH study newsworthy and issued a press release from its global headquarters based in Paris, France. This press release is the subject of the current complaint raised by Pfizer against Sanofi UK.

Scope of the Code – Clause 1.2
The press release contained information about medicines and was placed on the internet outside the UK. It was neither placed there by a UK company nor with a UK company's authority. The press release was placed on the internet by the Sanofi's global press office from its global headquarters in Paris, France. However, it does not make specific reference to the availability or use of a Sanofi medicine in the UK. For this reason, Sanofi does not agree that the press release falls in the scope of the ABPI Code.

This press release was not intended for a UK audience. All reasonable steps were taken by Sanofi global press office to prevent exposure of the press release to UK audiences and to ensure that no action was taken which would bring this activity under the scope of the ABPI Code.

We refer to the points raised in our letter dated 23rd September 2025, which we set out again below for ease of reference:

1. **International audience focus**: the press release was a global communication for international news media, that was not specifically targeted at UK healthcare professionals or the UK public.

2. **No UK-specific media targeting**: The press release was globally issued through news wire services. No UK-specific media were targeted for this press release by either global or local communications teams.

3. **No proactive localisation**: The press release was not adapted or localised for the UK audience. It remained in its global format without UK-specific localisation or contact information.

4. **No dissemination through UK social media**: We did not disseminate the press release or study results through UK social media channels, nor did anyone in the UK organisation engage with or amplify global posts. Communication was sent to all relevant employees to refrain from engaging with this press release on any social media outlet.

5. **Financial Times coverage**: We note Pfizer's concern about the re-post of the press release by the Financial Times. This was a direct syndication of the press release directly from the newswire – the source cited was Globe Newswire, which is a US-based newswire. Sanofi did not send this release directly to the Financial Times. To reiterate, no UK specific news vendors were proactively approached or targeted.

We respectfully request that the Panel agrees with Sanofi's submission that this press release is not within the scope of the ABPI Code as it does not refer to the use or availability of a Sanofi medicine in the UK and it was not directed at a UK audience. Alternatively, if the Panel concludes differently, we have provided further information below in response to the alleged breaches of the ABPI Code, as requested by the case preparation manager.

Clause 26.1
Sanofi disagrees that the press release promoted Beyfortus to members of the public. The press release was non promotional in nature, and was not disseminated to any UK trade or lay press and Sanofi UK did not engage with it on social media. The press release did not mention the use or availability of Beyfortus in the UK. Whilst it did mention that Pfizer's Abrysvo vaccine was being used in the UK, it is a well-established Code principle that a pharmaceutical company cannot be found to be promoting another company's medicines (AUTH/3774/6/23 – Complainant v AstraZeneca, AUTH/2785/8/15 - Anonymous consultant v Bayer and AUTH/3207/6/19 - Anonymous v Santen). We therefore deny breach of Clause 26.1 of the ABPI Code.

Clause 26.2
Pfizer claims that Sanofi UK made unbalanced and misleading information available to the public. The press release detailed the factual findings of a study accepted for presentation at an academic congress. Sanofi UK took all reasonable steps, in a globally connected world, to prevent dissemination of the press release to a UK audience. The press release was limited to the newsworthy findings from the REACH study. Sanofi UK refute that the press release made unbalanced and misleading information available to the public and deny breach of Clause 26.2 of the ABPI Code.

Clauses 6.1 and 6.2
Pfizer claims that Sanofi UK made unbalanced, misleading and inaccurate claims and comparisons. The press release focused on the outcomes of the REACH study which documented the findings of a study describing the public health impact of RSV prevention programs in the UK and Spain. Pfizer have raised concerns about the correct

study design for accurately measuring the public health impact of two immunisation strategies. Although Sanofi UK agrees that scientific debate, including on study design, increases rigor in public health decision-making, questions of study design fall within the remit of regulators, ethics committees and the scientific community and rather than the framework of the PMCPA. Sanofi UK deny a breach of Clause 6.1. Sanofi also deny breach of Clause 6.2 as the information contained within the press release was substantiated from the study itself.

Clause 6.6
Sanofi strongly supports public vaccination programs globally and in the UK. The REACH study contributes to the scientific understanding of different RSV prevention strategies. Scientific discourse and research are essential for advancing public health with evidence-based methodology, and presenting study findings does not constitute disparagement of the national program, Abrysvo or Pfizer. Sanofi UK therefore denies a breach of Clause 6.6 of the ABPI Code.

Clause 8.3
Sanofi UK confirms that the press release was examined, thereby refuting any breach of Clause 8.3.

Clauses 5.1 and 2
Sanofi UK believes that all reasonable steps have been taken to ensure that this press release does not breach the ABPI Code of Practice. The contents of the press release convey results from a real-world observational study of differing approaches used to minimise the public health impact of infant RSV. The press release was not intended for UK audiences. It was necessary to refer to the UK, as the location of the study is relevant to the interpretation of the data.

As an organisation, Sanofi is committed to the highest standards of ABPI Code compliance, and we do not believe this press release amounts to a failure by Sanofi to maintain such high standards in light of the points set out in this letter. Sanofi refutes any breach of Clause 5.1 or Clause 2 of the ABPI Code.

Conclusion
Although UK audiences may inevitably access information published globally on the internet, applying the ABPI Code extraterritorially would be unacceptable in cases where there is no specific targeting of UK audiences.

The REACH study press release is a global communication issued by Sanofi's global headquarters registered in Paris, France. It conveyed the newsworthy study results and neither targeted the UK audience nor referenced the use or availability of a Sanofi medicine in the UK.

Sanofi UK denies all alleged breaches of the ABPI Code set out in Pfizer's complaint. We respectfully request that the Panel dismisses this complaint and rules that the activity falls outside the scope of the ABPI Code.

Thank you for your consideration of this matter. We remain available to provide any further information or clarification the Panel may require."

FURTHER INFORMATION REQUESTED FROM SANOFI BY THE PANEL

The Panel began considering this case but decided it needed more information from Sanofi. On 11 March 2026, it wrote to Sanofi as follows:

> "Can you please confirm how and to whom the press release was disseminated? You mention in your response that "The press release was globally issued through news wire services. No UK-specific media were targeted for this press release by either global or local communications teams."
>
> Please could you provide further information on the "news wires services" (who they are specifically, how they work and who they disseminate information too). Could you please also clarify which specific media were targeted for this press release, and by whom?
>
> Please also provide any information you may have on geotargeting that was linked to its dissemination. Lastly, please provide a copy of the REACH study."

The response from Sanofi is reproduced below:

> "I write in response to your email dated 11/3/2026 and regarding the distribution lists used for global announcements.
>
> The distribution for this press release followed a distribution mechanism which reflects **standard practice for publicly listed companies across all industries**. Sanofi is listed on **Euronext Paris** and therefore operates under market rules requiring **fair, simultaneous and non-discriminatory dissemination of potentially material corporate information**.
>
> For this reason, global press releases are to be distributed through an established and market authority-approved international newswire services such as **GlobeNewswire**, which are designed precisely to ensure broad access to corporate information across media, investors and market participants. This includes:
>
> - journalists and media outlets (some upon their request to opt in)
> - financial analysts
> - institutional and individual investors and shareholders
> - competitors and peers
> - and individuals who subscribe to receive corporate announcements on their own.
>
> As part of normal corporate disclosure practices, the release was also distributed to international news agencies such as AFP, Bloomberg and Reuters. These agencies operate global editorial networks and redistribute information to their own subscribers worldwide. The geographic location of individual journalists receiving the information is therefore **outside of Sanofi's control**.
>
> Last and more importantly, in this specific press release case:
> - **No UK media outlets were directly targeted** by either the global or the UK communications teams
> - **No proactive engagement or outreach** was conducted to UK journalists before or after the distribution

The press release was therefore treated as a **global corporate communication**, and never as a communication intended for the UK market.

In response to your second question; The manuscript for the REACH study is not yet available; I am, therefore, attaching the slide deck presented by the author at the ESPID congress.

If you have any further enquiries regarding Case/0688/08/25 please do not hesitate to contact me directly."

PANEL RULING

This case was in relation to a press release issued by Sanofi's global headquarters in Paris in connection with the presentation of the REACH study at the European Society for Paediatric Infectious Disease (ESPID) congress on 29 May 2025.

The REACH study considered RSV-related infant hospitalisations in the UK and Spain before, and after, the introduction of two different approaches to preventing RSV:

- immunisation of infants after birth with Sanofi's Beyfortus (nirsevimab) in Spain, and
- immunisation of pregnant women to provide protection to infants from birth using Pfizer's maternal RSV vaccine, Abrysvo (RSVpreF), in the UK.

Pfizer's maternal RSV vaccine had been chosen for the UK's national immunisation programme. Sanofi's product, Beyfortus (administered to neonates and infants), had been chosen for national RSV immunisation programmes in other European countries, including Spain.

Pfizer alleged that the press release made misleading and scientifically flawed claims and comparisons, disparaged the UK maternal RSV vaccination programme and Pfizer's vaccine, and promoted a prescription only medicine to the public.

Sanofi's response to the complaint was essentially that the press release was outside the scope of the Code because it was a global communication issued from its Paris headquarters, and was not targeted at a UK audience.

The Panel accepted that it was an established principle of the Code that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code.

The Panel first dealt with the question of whether the press release fell within the scope of the Code before considering the substantive allegations.

Whether the press release was within the scope of the Code

The Panel considered, in general terms, that whether international activities or materials came within the scope of the UK Code, would be decided on a case-by-case basis bearing in mind, amongst other things, the UK nexus and, if relevant, the requirements of Clause 1.2.

Clause 1.2 of the Code stated:

> “Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:
>
> • a UK company/with a UK company’s authority, or
>
> • an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK.”

The Panel considered Clause 3.4 which stated:

> “Companies must comply with all applicable codes, laws and regulations to which they are subject.”

The supplementary information to Clause 3.4 also included the following:

> “Compliance with all applicable codes, laws and regulations to which a pharmaceutical company is subject is particularly relevant when activities/materials involve more than one country or when a company based in one country is involved in activities in another country.
>
> Activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities take place or the materials are used.”

Sanofi submitted that the press release was a global communication issued through international newswire services, not adapted or localised for the UK, and not actively targeted at UK media outlets or UK healthcare professionals. Sanofi argued that it had taken all reasonable steps to limit UK exposure and that it would be disproportionately unfair to subject global communications of this nature to the requirements of the UK Code.

The Panel accepted that this was not a straightforward matter and that Clause 1.2 did not deal specifically with the issue of global press releases that refer to *other* companies’ medicines in the UK. It could be argued that Clause 1.2 was primarily concerned with information or promotional material that a company places on the internet about its own medicines.

However, on balance, the Panel concluded that Sanofi’s global press release fell within the scope of the Code for the following reasons.

1. The definition of promotion at Clause 1.17 of the Code defines promotion as “any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of **its** medicines.” (Panel’s emphasis). It is therefore not possible under the Code for a company to promote *another* company’s medicine. However, Clause 1.2 refers to “information”; not just promotional material. The Panel considered it to be an established interpretation of the Code that "information" can encompass information about another company's medicine; not just information about the issuing company's medicine. Clause 1.2 referred to "specific reference to the availability or use of **the** medicine in the UK”

(Panel's emphasis), therefore the Panel concluded that this clause was not confined to information about a company's own products.

2. The press release contained specific and prominent information about the efficacy and use of Pfizer's vaccination in the UK. References to the UK appeared in the first sub-heading and first main paragraph of the press release, in the context of a direct and unfavourable comparison of the UK vs the Spanish immunisation programme. Given the strong and unequivocal nature of the comparison, together with heightened public interest in vaccine efficacy and the clear UK nexus, the Panel considered that these references would inevitably attract the interest of a UK audience, including journalists. Although it was a global press release, it clearly had a meaningful UK dimension and, given the nature of the comparison, it was therefore foreseeable that it would encourage UK engagement in particular.

3. The Panel considered the core purpose of the press release. Its central focus was to announce the publication of data which compared the nirsevimab vaccination programme in Spain with the maternal RSV vaccination programme in the UK. In the Panel's view, to accept Sanofi's submission that such a press release fell outside the scope of the UK Code would risk allowing companies to circumvent the requirements of the Code given the clear UK references and in particular the nature of the comparison in the press release. The Panel considered that Sanofi's submission on this UK nexus point was not a correct interpretation of the Code's purpose, scope or spirit.

4. Sanofi accepted in its submission that the press release was global in scope and therefore did not exclude a UK audience. Whilst Sanofi stated that the press release was intended for an audience outside of the UK, the Panel noted that the press release itself was silent about its intended audience. The Panel also considered the fact that the REACH study focused on the UK public vaccination campaign, made it inherently newsworthy in the UK. In the Panel's view, it was reasonably foreseeable that a UK audience in particular would be likely to seek out and engage with its findings. The Panel's conclusion on this point was validated by the fact that the press release was reported on in the Financial Times (a major mainstream UK publication), via syndication from the newswire.

The Panel did not accept Sanofi's submission that deciding the press release was within scope of the Code would give the Code extraterritorial reach. The Panel decided the Code applied because of the press release's UK nexus, its specific and prominent references to the UK programme, the foreseeable UK audience interest, and the actual UK media interest that followed.

For all these reasons, the Panel concluded that the press release fell within the scope of the Code. The Panel therefore proceeded to consider the substantive allegations.

The allegations

Pfizer alleged breaches of the following clauses of the Code:

- Clause 6.1 – making unbalanced, misleading and inaccurate claims and comparisons
- Clause 6.2 – making claims and comparisons that cannot be substantiated by scientific evidence

- Clause 6.6 – making disparaging comments about the UK maternal national immunisation programme and the use of Pfizer's RSV vaccine in the programme
- Clause 26.1 – promoting a prescription only medicine to the public
- Clause 26.2 – making unbalanced and misleading information available to the public
- Clause 8.3 – failing to examine a press release that is in scope of the Code
- Clause 5.1 – failing to maintain high standards
- Clause 2 – bringing discredit upon, and reducing confidence in, the pharmaceutical industry

Sanofi's response

In relation to the substantive allegations, Sanofi's position was, in summary, that:

- the REACH study was a legitimate piece of scientific research presented at an international congress,
- the press release was non-promotional in nature and consistent with standard practice for disseminating clinical trial results,
- the REACH study contributed to scientific discourse about different RSV prevention strategies, and
- presenting study findings did not constitute disparagement of any national programme.

Information, claims, comparisons and disparagement (Clause 6)

The relevant provisions relied upon 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."

The Panel interpreted Pfizer's allegations under Clause 6 as being directed principally at the performance of nirsevimab in Spain compared to the performance of the maternal RSV vaccination programme in the UK, and the scientific limitations of the REACH study's methodology as it applied to the UK.

The comparative claims at issue, in the first two paragraphs of the press release, read:

> “Late-breaking data show infant respiratory syncytial virus (RSV) hospitalizations reduced by 69% in Spain following Beyfortus-only immunization targeted to all infants and 26.7% in the UK following RSVpreF-only maternal vaccination”
>
> and

> "An immunization program implemented in Spain using Beyfortus cut infant hospitalizations due to RSV by 69.0% during the 2024-2025 RSV season compared to the 2022-2023 season, according to data presented at the 43rd Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) in Bucharest, Romania. The real world analysis also showed that a program in the UK using only the RSVpreF maternal vaccine reduced infant RSV hospitalizations in infants by 26.7% over those same RSV seasons."

These sat beneath the heading of the press release:

> "Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs"

Pfizer submitted that a valid evaluation of the impact of the UK maternal vaccination programme in any study, must account for:

1. the timing of the programme's introduction,
2. expected timing of births based on the gestational age window of the programme, and
3. the expected attained age of infants eligible for protection within the study period.

The Panel accepted that submission for the reasons set out below.

Misleading comparisons that cannot be substantiated (Clause 6.1 and Clause 6.2)

The UK maternal RSV vaccination programme was introduced in Scotland on 12 August 2024 and in England on 1 September 2024 for women who were 28 weeks pregnant or beyond. The Panel accepted that the oldest infants who could have benefitted from the programme would only have been a few months old by the end of the REACH study period of 31 March 2025. Many infants included in the UK arm of the analysis would not have been eligible to benefit from the programme at all, inevitably impacting the hospitalisation data. Comparing those infants with a cohort in Spain, *all* of whom had received nirsevimab after birth, was, in the Panel's view, not a valid comparison.

Although Sanofi informed the Panel that the REACH study manuscript was not yet available at the time it considered this case, the Panel acknowledged that the REACH study data was presented at the ESPID congress in May 2025, approximately three or four months after the date of the materials that were ruled in breach in Case/0689/08/25. However, the Panel considered that, even by May 2025, the data from the UK arm of the study still did not cover a sufficient period to allow valid comparisons and conclusions under the Code to be drawn about the maternal vaccine's population-level impact. Sanofi provided no additional data to support the comparison (other than a slide deck on the REACH study presented by its author at the ESPID congress), and the Panel noted that the study period did not encompass a complete winter RSV season for infants who could have benefitted from the UK programme. The Panel considered that the comparison presented in the press release was accordingly misleading and not capable of substantiation. For these reasons, the Panel ruled **breaches of Clause 6.1 and Clause 6.2.**

Referring to relative risk but not absolute risk (Clause 6.1)

Pfizer also alleged that the press release quoted only relative risk reductions without providing absolute risk reductions. The supplementary information to Clause 6.1 stated that “relative risk should never be referred to without also referring to the absolute risk”.

The Panel considered the nature of the percentages presented in the press release. The figures cited (a 69% reduction in infant RSV hospitalisations in Spain and a 26.7% reduction in the UK) appeared to the Panel to be a percentage reduction in the rate relative to a comparator group or baseline period. The absence of absolute risk rates, and the lack of sufficient trial detail or explanation to allow readers to contextualise the relative risk cited, added to the misleading nature of the press release. In the Panel’s view, the material was not sufficiently complete to enable recipients to form their own view of the data or to understand the comparison between the two products. Consistent with well-established principles applied in PMCPA case precedent (for example AUTH/3760/04/23 and Case/0272/08/24 concerning Covid-19 vaccine communications), the Panel considered that omitting absolute risk data alongside relative risk data made the comparison misleading. The Panel therefore ruled a **breach of Clause 6.1**.

Disparagement of the UK immunisation programme and Pfizer's RSV vaccine (Clause 6.6)

In considering Clause 6.6, the Panel took account of Pfizer's allegations of disparagement being founded on the same date-related issues that underpinned its Clause 6.1 and Clause 6.2 allegations. The Panel accepted that the comparison in the press release was misleading for the reasons set out above.

The Panel considered it to be an inevitable consequence of the nature of the unfair comparison that the UK vaccination programme (and, by association, Pfizer’s medicine) had been disparaged. It was disparaging of Pfizer’s maternal vaccine because it was being presented in such a way as to suggest that it did not work very effectively (a 26.7% reduction in hospitalisations in the UK, compared to a 69% reduction in Spain), even though that conclusion was based on incomplete UK data given the point in time at which the UK maternal vaccine had first been given to pregnant women.

In addition, the Panel bore in mind the strong and definitive conclusion of the press release that “Beyfortus is well accepted by parents and providers and remains the only option that can offer RSV protection designed for all infants with proven high, sustained efficacy, favorable [sic] safety and public health impact demonstrated in the real world”, which the Panel considered compounded the initial misleading implication of the superiority claims at issue. The Panel ruled a **breach of Clause 6.6**.

Promoting a prescription only medicine to the public (Clause 26.1)

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."

Pfizer alleged that the press release promoted Beyfortus to the public.

It was not in dispute that the press release was directed to the media who would disseminate its content to the general public. The Panel accepted that it was possible for press releases to refer

to medicines, so long as the subject matter of the press release was newsworthy and the content otherwise complied with the Code. It appeared to the Panel that Pfizer's allegation was that the unfair comparison rendered the press release promotional. The Panel considered that its rulings of breaches of Clause 6.1 and Clause 6.6 did not automatically render a press release promotional; whether it was promotional would depend on context and the specific wording of the press release in question. The Panel bore in mind its reasons for the breaches of Clauses 6.1 and 6.6 set out above.

The Panel acknowledged that the press release was, in essence, a communication about the results of a clinical study presented at a scientific congress. The Panel took account of the title of the press release and the very first bullet point:

> "Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs
>
> - Late-breaking data show infant respiratory syncytial virus (RSV) hospitalizations reduced by 69% in Spain following Beyfortus-only immunization targeted to all infants and 26.7% in the UK following RSVpreF-only maternal vaccination"

By claiming at the very outset of the press release that a "public health advantage" was being bolstered as a result of the REACH study (when that claim was based on a misleading yet unequivocal comparison of two stark percentages in Spain and the UK), the Panel considered that Sanofi had used promotional language and misleading data to unfairly and prominently place Beyfortus in a favourable light compared to Pfizer's vaccine. On balance, the Panel therefore concluded that the press release amounted to advertising a prescription only medicine to the public and ruled a **breach of Clause 26.1**.

Making unbalanced and misleading information available to the public (Clause 26.2)

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 considered that the press release was accessible to members of the public, having been distributed via international newswire services. It therefore constituted information about prescription only medicines made available to the public within the meaning of Clause 26.2.

For the reasons set out above in relation to Clauses 6.1 and 6.2, the Panel considered that the information made available to the public about the comparison between Beyfortus and the UK maternal RSV vaccine programme was not accurate or balanced. The misleading comparison between the Spanish and UK programmes, and the absence of any acknowledgement of the significant limitations of the UK arm of the REACH study, meant that the press release was presented in a way that the Panel considered was unbalanced and misleading. The Panel ruled a **breach of Clause 26.2**.

Certification of a press release (Clause 8.3)

Clause 8.3 provides that certain types of non-promotional material must be certified in a similar manner to the certification of promotional material under Clause 8.1; press releases do not fall within the categories listed. The Panel noted the reference to press releases in the supplementary information to Clause 8.3 (under the heading "Examination of Other Materials") as an example of non-promotional material that should be examined.

The Panel relied upon its ruling above in which it had concluded that the press release was promotional and therefore advertised a prescription only medicine to the public contrary to the requirements of Clause 26.1. On this narrow technical basis (that the press release was promotional), the Panel ruled **no breach of Clause 8.3.** However, the Panel took account of the failure to examine the press release as part of its Clause 5.1 ruling below.

High standards (Clause 5.1)

The Panel considered that the failures identified in relation to all of the breach rulings above demonstrated that Sanofi had not exercised the caution required when making claims and comparisons about public health vaccination campaigns, where accuracy was especially important. The potential audience for the press release included UK health professionals, decision makers, and members of the public with an interest in RSV immunisation, and it was therefore very important that the comparison presented was fair, balanced and substantiated.

The Panel also took into account that Sanofi had not provided evidence that it had considered the UK dimension of, and interest in, the press release (beyond this being a "global press release"). Sanofi had not taken steps to define or restrict that audience in a way that would have addressed the UK dimension of the press release. The press release was silent about its intended audience. Additionally, given Sanofi had considered the press release to be out of scope of the Code, there had been no consideration of the requirements of the supplementary information to Clause 8.3 of the Code regarding examination of the material. Taken together, these matters demonstrated a failure to maintain the high standards and the Panel ruled a **breach of Clause 5.1**.

Discrediting the industry (Clause 2)

Clause 2 was a sign of particular censure and was reserved for cases where a company had brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel took the view that its rulings about the press release in this case concerned one comparison, and were therefore not as broad as the Panel's rulings and concerns in the related Case/0689/08/25, for which Sanofi had also been reported to the Appeal Board. Nevertheless, the Panel considered carefully whether the circumstances of this case met the threshold for a Clause 2 ruling in its own right, rather than by comparison with Case/0689/08/25.

On balance, the Panel concluded that this case did warrant a Clause 2 breach ruling for the following reasons.

1. The misleading comparison at the heart of this case was particularly serious. At the time the press release was issued, its key message and bold comparison of UK data

compared to Spain was premised on UK data that was not yet sufficiently complete for such comparisons to be made.

2. Given 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.

3. Vaccination programmes play a critical role in reducing and eliminating infectious diseases. So that public confidence in immunisation efforts can be maintained, it is particularly important that these programmes are not undermined.

4. The supplementary information to Clause 2 lists “prejudicing … public health” as an example of an activity that is likely to be in breach of that clause. Given the UK context of a declining uptake in vaccines, the Panel viewed the circumstances of this case as a potential public health concern.

The Panel therefore considered that the threshold for bringing discredit upon, or reducing confidence in, the pharmaceutical industry, had been reached in this case and ruled a **breach of Clause 2**.

Complaint received **11 August 2025**

Case completed **17 June 2026**