CASE/0958/05/26 ***NO BREACH OF THE CODE***

COMPLAINANT v SANOFI

Allegations about a Multiple Sclerosis campaign

CASE SUMMARY

This case was in relation to a Sanofi produced and funded LinkedIn post for a resource on smouldering multiple sclerosis (MS) for health professionals. The complainant alleged that, at the time of the complaint, Sanofi had a new medicine for non-relapsing secondary progressive multiple sclerosis (nrSPMS) that had received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) and that this medicine was the only new treatment for this patient population. In the complainant's view, the link between Sanofi's new treatment and the smouldering MS campaign was explicit and inappropriate as it promoted a medicine prior to the grant of its marketing authorisation

The outcome under the 2024 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon or reduce confidence in the pharmaceutical industry**
No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply**
No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1	**Requirement that companies must maintain high standards at all times**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of the marketing authorisation that permits its sale or supply**

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 was received about Sanofi from an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

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

> "I am concerned that Sanofi's smouldering MS campaign is disguised promotion, promotion prior to a licence being granted and promotion to the public. They have a new molecule for nrSPMS [non-relapsing secondary progressive multiple sclerosis] recently with a positive opinion from the CHMP and I would assume the MHRA are reviewing for a UK licence. This is the only new treatment for this patient population and therefore the link between their campaign and this new drug is for me explicit and inappropriate. I'm disappointed Samofi [Sanofi] feel this campaign is suitable. I would ask the panel to consider clauses 2, 5, 11, and any other I may have missed"

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 3.6, 5.1, 11.1 of the 2024 Code.

SANOFI'S RESPONSE

The response from Sanofi is reproduced below:

> "We are writing in response to the complaint received regarding a targeted LinkedIn advertisement created and funded by Sanofi UK, which directed healthcare professionals (HCPs) to disease state education content on smouldering multiple sclerosis (MS). Sanofi takes such matters very seriously and we appreciate the opportunity to provide a comprehensive response addressing all concerns raised.
>
> We understand that the PMCPA has asked us to address the following alleged breaches of the 2024 ABPI Code of Practice:
>
> - Breach of Clause 2
> - Breach of Clause 3.1
> - Breach of Clause 3.6
> - Breach of Clause 5.1
> - Breach of Clause 11.1
>
> We strongly deny all these allegations. The disease state education campaign in question was non-promotional, scientifically valid, and conducted in full compliance with all applicable clauses of the 2024 ABPI Code of Practice.
>
> We attach to this response a copy of the LinkedIn advertisement in question and its certification, and a copy of materials accessed through the advertisement and their certifications (. Please find below the evidence and reasoning that substantiates our position.
>
> **1. Scientific Validity and Educational Merit of Smouldering MS Education**
> Multiple Sclerosis consists of two concurrent disease processes, acute and smouldering neuroinflammation. The latter is often referred to as progression independent of relapse activity (PIRA). Smouldering MS is a scientifically recognised pathophysiological process that has been the subject of extensive peer-reviewed research and international academic discourse. It is not a novel or speculative concept

introduced by Sanofi; it is a fundamental and increasingly recognised aspect of MS pathobiology. This represents a genuine unmet need in the understanding of MS. There is a disconnect between the academic understanding of MS and the approach by the clinical community. Neurologists, MS specialists, and allied healthcare professionals need to understand this concept to appropriately counsel patients demonstrating the educational need is real, recognised, and independent of any specific therapeutic pipeline.

The landmark paper by Giovannoni et al. (2022), *'Smouldering multiple sclerosis: the "real MS"'* provides a comprehensive synthesis of pathological, neuroimaging, and clinical evidence to argue that the 'real MS' is driven primarily by a smouldering pathological disease process. The lead author is an eminent UK clinician, and the authors are a pan-European group of leading MS neurologists, challenging the dominant view that defines MS solely as a focal acute inflammatory disease. They present compelling evidence that the progressive accumulation of disability in MS can occur independently of relapse activity from early in the disease course and disability is present from the very early stages of the disease and is therefore not specific to secondary progressive MS (SPMS). This supports a biological continuum between relapsing and progressive stages of MS. Sanofi Genzyme provided financial support to adapt and design the figures, and for a third party to help coordinate the submission of this manuscript. At no stage did any Sanofi Genzyme staff have input into the writing and editing of the paper.

2. Non-Product-Specific Nature of the Campaign

The disease state education campaign is intended to address fundamental disease biology, balancing the concepts of the two disease processes referenced above, the concept of smouldering MS, the role of microglia, and the mechanism of BTK (Bruton's Tyrosine Kinase) in the pathophysiology of smouldering MS. There is no mention of the inhibition of BTK and the content is not tailored to, and does not reference, any specific product. The educational content prepares the MS clinical community for a deeper understanding of the disease processes within MS, a shift that is driven by the scientific evidence, not by Sanofi's commercial interests. Sanofi is one of many companies investigating smouldering disease.

3. Tolebrutinib Regulatory Status and Timeline: Significant Distance from Launch

The complainant and PMCPA refer to a 'molecule' and details regarding the licensing status of this asset. For contextual purposes we are providing details surrounding our phase 3 asset tolebrutinib which is due to be licensed in the SPMS population. Tolebrutinib is currently in phase 3, undergoing regulatory review with the EMA. The regulatory and reimbursement timeline for tolebrutinib in the UK demonstrates clearly that Sanofi UK is not close to launching this product, there is no regulatory review being undertaken by the MHRA. The following chronology is relevant and supported by publicly available press releases and regulatory communications.

Date	Event
December 2025	Tolebrutinib not approved by the FDA for SPMS
December 2025	Tolebrutinib failed the Phase 3 Perseus trial in primary progressive MS (PPMS)

3 March 2026	LinkedIn advertisement went live
April 2026	Tolebrutinib received a positive CHMP opinion from the EMA
May 2026 (current)	Awaiting final EMA approval — not yet approved No confirmed date for MHRA submission

4. Declaration of Involvement

The advertisement was distributed exclusively through LinkedIn, a professional networking platform and stated, 'Intended for UK Health Care Professionals Only'. The advertisement was clearly and unambiguously Sanofi owned and branded. Whilst Sanofi engaged a third-party agency to support the technical configuration and execution of the advertisement's backend targeting parameters, the content and messaging remained entirely under Sanofi's ownership. Upon entering the webpage, the declaration 'This site is created and funded by Sanofi' is at the top of each webpage, in addition to a large Sanofi banner on the bottom of each webpage.

5. Robust Gatekeeping and Appropriate Audience Targeting

Sanofi implemented multiple layers of gatekeeping to ensure that the disease state education content was clearly targeted to appropriate UK-based HCPs. The advertisement itself states it is intended for UK HCPs only. We have outlined our approach below.

5a. LinkedIn Targeting Parameters

The paid LinkedIn advertisement was targeted using the following parameters .

Locations (Permanent): United Kingdom only
Job Titles (Current): Doctor, Neurosurgeon, Resident Doctor, Physician Assistant, Medical Doctor, Neurology Resident, Paediatric Neurologist, Neurology Technician, Medical Specialist, Director of Neurology, Assistant Director of Neurology, Specialist, Neurologist
Member Skills: Multiple Sclerosis, Neurologists, Neurological Disorders, Neurology, Neurological Rehabilitation, Neurological Surgery, Neurology Nursing
Member Age: 25 to 34, 35 to 54, 55+ (i.e., adults of working age consistent with qualified HCPs)
Company Industries: Hospitals and Health Care

These targeting parameters were carefully selected to ensure that the advertisement reached only UK-based healthcare professionals with relevant clinical expertise in neurology and MS. The targeting parameters employed 'AND' logic between each title highlighted in bold above, requiring viewers to meet all specified professional criteria simultaneously, thereby ensuring heightened precision in audience targeting.

5b. Additional Gatekeeping: Self-Certification

Beyond the LinkedIn targeting, a further layer of gatekeeping was implemented at the point of access to the disease state education website. Users were required to self-certify once prompted with the following pop up, 'This is a non-promotional disease education website provided by Sanofi and is intended for UK healthcare professionals only. Please click the appropriate button below'. Upon confirming they are a UK-based healthcare professional this would enable access to the landing page and educational content. This self-certification requirement ensured that even if a non-HCP were to

encounter the advertisement through the LinkedIn targeting, they would be unable to access the substantive educational content without actively confirming their professional status.

If a member of the public were to confirm they are not a UK HCP, they would be directed away from the disease education campaign website to the Sanofi UK corporate home page.

The dual-verification approach with LinkedIn professional targeting combined with self-certification represents a robust and proportionate gatekeeping mechanism for non-promotional disease state education intended for HCPs placed on a social media platform.

6. Compliance with ABPI Code Clauses
We address each alleged breach in turn.

Clause 3.1 & 11.1
Tolebrutinib was never mentioned, named, or referenced in any of the campaign materials or the LinkedIn advertisement. The campaign focused entirely on disease biology and pathological mechanisms.
For a campaign to constitute promotion of an unlicensed medicine, there must be some connection, direct or indirect, between the campaign and the specific product. No such connection exists here. The educational content addressed:

- The concept of smouldering MS and PIRA as a primary disease process
- The role of microglia in progressive biology
- Broader pathophysiological processes involved, one of which was the mechanism of BTK in microglial activation
- The duality of acute and smouldering neuroinflammation and the need to move from a purely acute-centric model

Furthermore, the significant distance from any potential UK launch of a molecule means that the campaign cannot reasonably be characterised as pre-launch promotional activity. We refer the PMCPA to the regulatory timeline set out in Section 3 above.

Clause 3.6
The campaign was openly and transparently created by Sanofi UK. Clear Sanofi branding was present on the LinkedIn advertisement and on the disease state education website. There was no attempt to conceal Sanofi's involvement or to present the campaign as independent scientific content. Appropriate audience targeting and gatekeeping measures were implemented, as described in Section 5 above.

Clause 5.1
All materials underwent rigorous internal review and approval processes in full accordance with Sanofi UK Standard Operating Procedures for the review and approval of materials by a final medical signatory with certification attached. All employees are required to adhere to the local Standard Operating Procedure (SOP) regarding personal social media use which determines engagement with any paid LinkedIn advertisements, we attach for reference.

Clause 2
The smouldering MS disease state education campaign was conducted with the highest standards of transparency, scientific rigour, and ethical conduct. All content was evidence-based and referenced to peer-reviewed publications. The campaign enhanced rather than undermined public trust in the industry, and the dual-verification approach represents a precautionary measure beyond the requirements of the code, given the content was non-promotional and intended for HCPs but available via a professional social media network.

Voluntary Admission
We wish to inform the PMCPA that upon notification of this complaint we identified an expired video (expired 04/03/26) during the post-complaint investigation. The video sits within the disease education campaign and therefore entirely non-promotional. The certificate for this asset shows 'expired' as this reflects the current status in PromoMats. However, this video was certified within the context of the website and at the time of certification of the relevant webpage the video asset had not yet expired.

Our subsequent action has been to voluntarily suspend the LinkedIn advertisement, and we have temporarily taken down the associated educational website content by the 15/05/26. Recertification has been paused whilst we address the complaint. We believe the root cause of this expired asset is the departure of two content owners without appropriate material reassignment. We have a robust framework in place to ensure the compliant management of materials post-approval. We regularly update the business on the SOP 'Management of Materials post-PromoMats approval', however further preventative measures are being taken including targeted training of the SOP to all internal PromoMats users to reinforce compliance with these requirements. Our action to suspend the campaign reflects our commitment to maintaining the highest standards of conduct while this matter is under review.

Conclusion
We trust that our response, supported by the enclosed evidence, demonstrates clearly that the LinkedIn disease state education campaign on smouldering MS was a non-promotional educational initiative conducted in full compliance with the 2024 ABPI Code of Practice.

In summary:

- Smouldering MS is a well-established scientific concept with genuine educational merit, supported by extensive peer-reviewed literature. The educational need for HCPs to understand the evolution in disease understanding is real and independent of any specific therapeutic pipeline.
- The campaign was balanced in nature, contained no product-specific content and made no reference to any Sanofi pipeline asset. The content addressed disease biology relevant to multiple pipeline products across the industry
- The regulatory and commercial timeline for tolebrutinib demonstrates that Sanofi is not close to launching this product in the UK and that no near-term commercial benefit could be derived from this campaign.
- Robust gatekeeping and appropriate audience targeting were implemented, including LinkedIn professional targeting parameters and self-certification, ensuring the content was intended only to UK-based HCPs.

- The campaign was transparently created by Sanofi UK, with clear non-promotional branding throughout. There was no attempt to disguise Sanofi's ownership or the educational nature of the content.
- All materials were reviewed and certified in accordance with Sanofi's internal SOPs and the requirements of the 2024 ABPI Code.

We strongly deny all alleged breaches of Clauses 2, 3.1, 3.6, 5.1, and 11.1 of the 2024 ABPI Code of Practice, and we are confident that this campaign was conducted to the highest standards of ethical conduct and Code compliance. Sanofi remains committed to these standards in all its activities and to contributing meaningfully to the education of the healthcare community in the interests of patients living with MS."

FURTHER INFORMATION FROM SANOFI

Sanofi's response to a request from the Panel for further information is reproduced below:

"Thank you for your letter requesting further information. We are committed to providing a prompt and comprehensive response to support the Panel's review.

Please find below the information request:

1. **Date of European Commission Adoption of CHMP Positive Opinion**
   The CHMP adopted a positive opinion on 24 April 2026. Final EMA approval was granted on 23 June 2026.

2. **Licenced Indication for Tolebrutiniib as Granted by EMA**
   For the treatment of adults with secondary progressive multiple sclerosis (SPMS) without relapses in the last 2 years

3. **Copies of All Videos on the Smouldering MS Website and Certificates**
   [List of unique identifiers correlating to smouldering MS website materials]

We trust this information assist the Panel in its consideration of this case.

Should you require any clarification or additional documentation, please do not hesitate to contact us."

PANEL RULING

This case was in relation to a Sanofi produced and funded LinkedIn post for a resource on smouldering multiple sclerosis (MS) for health professionals. The complainant alleged that, at the time of the complaint, Sanofi had a new medicine for non-relapsing secondary progressive multiple sclerosis (nrSPMS) that had received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) and that this medicine was the only new treatment for this patient population. In the complainant's view, the link between Sanofi's new treatment and the smouldering MS campaign was explicit and inappropriate as it promoted a medicine prior to the grant of the marketing authorisation.

The LinkedIn post and smouldering MS educational website

The LinkedIn post was headed “Smoldering MS” and comprised:

- a statement at the outset that the post was intended for UK healthcare professionals only,
- the body text which read *“Even when RRMS* (relapsing-remitting multiple sclerosis) *patients appear stable, smouldering neuroinflammation can cause gradual disability accumulation prior to SPMS diagnosis”*,
- an image of the smoking head of a match, which resembled a brain adjacent to the statement *“EXPLORE THE IMPACT OF SMOULDERING NEUROINFLAMMATION IN MS* and,
- a call to action which read “*Uncover the gradual signs of MS disability”* accompanied by a “*Learn more”* button which directed readers to the “smoldering MS” website.

A statement that the post was produced and funded by Sanofi appeared in the top right-hand corner of the post and ‘Sanofi’ also appeared towards the bottom of the post.

Sanofi submitted that the LinkedIn post was for UK health professionals only and provided details of the LinkedIn targeting criteria.

The Panel considered that any material associated with a post, for example, a link within a LinkedIn post, would normally be regarded as being part of that post. Therefore, the Panel concluded that the content of the smouldering MS educational website was relevant to its determination of whether Sanofi had promoted a medicine prior to the grant of a marketing authorisation.

The Panel understood that when a reader clicked “*Learn more”* they were directed to the smouldering MS website. When first accessing the website, the user was prompted with a self-attestation pop-up which stated that the website was non-promotional disease education provided by Sanofi intended for UK health professionals only and asked them to confirm their status as such. Sanofi submitted that users who confirmed they were not a UK health professional were directed to the Sanofi UK corporate website.

The smouldering MS website included the title smouldering neuroinflammation and a banner at the top of all pages which stated that the website was intended for UK health professionals only and was produced and funded by Sanofi. The Panel considered that given the content of the post, the pop-up box and signposting sufficient safeguards were in place such that the material had been directed at health professionals, rather than members of the public.

Beneath the banner referred to above was a navigation banner which contained buttons for Home, PIRA (progression independent of relapse activity), Disability Accumulation, and Considering Both Processes and Patient Stories and Resources. The content of the webpages was as follows:

a. <u>Home</u>

The Home page included a banner featuring the same stylised matchhead from the LinkedIn post alongside the statement *“ONCE SPARKED, SMOULDERING NEUROINFLAMMATION IS DESTRUCTIVE. Starting at the onset of multiple sclerosis (MS) smouldering neuroinflammation continues to cause damage, which can manifest over time as gradual disability accumulation”.* This statement was followed by a link to

learn more about the evidence which the Panel assumed would direct the reader to the disability accumulation section of the website.

Beneath the banner there were three tiles: one for acute and smouldering neuroinflammation; disability accumulation; and considering both processes. Each contained a sentence relevant to that topic and a link which the Panel assumed, directed the reader to the corresponding section of the website.

Finally, the home page contained a video of a patient story described as being inspired by a real patient and a link to hear more patient stories.

b. PIRA

The first PIRA page stated that "*Many people with MS continue to accumulate disabilities across the MS spectrum"* and *"Progression independent of relapse activity (PIRA) is an established phenomenon in relapsing-remitting multiple sclerosis (RRMS)".* Subsequent text referred to the presence of an ongoing process unrelated to relapses and described PIRA as an established phenomenon. This was followed by four graphics displaying data for PIRA including that PIRA is responsible for up to 80%-90% of disability accumulation in treated RRMS patients, PIRA can be seen in treated RRMS patients as early as 3 years after diagnosis, 65% of RRMS patients reported experiencing PIRA and, approximately 30%-40% of treated patients will transition to SPMS within12 years of RRMS diagnosis.

Beneath the heading *"The relapse-independent process remains unaddressed"* a graph compared the expanded disability status scale (EDSS) score over time in PIRA compared to relapse. The page concluded with a 'Hear from the experts' link and a 'Keep Exploring' link.

c. Disability Accumulation

The disability accumulation section of the website comprised three pages. The first page focused on the pathophysiology of acute and smouldering MS and the role of microglia as "*key orchestraters of smouldering neuroinflammation in the CNS"*. The second page described the role of smouldering neuroinflammation as a driver for disability accumulation over time in situations where acute neuroinflammation may decrease. The final page of the section was concerned with the importance of proactive ongoing monitoring of patients with smouldering neuroinflammation. The page included a list of physical and cognitive changes that may appear early as a result of smouldering neuroinflammation, and information on some nonpharmacological interventions to manage disability accumulation and improve quality of life.

d. Considering Both Processes

This webpage looked at the concurrent pathways of acute and smouldering neuroinflammation. The page included a graphic of the central nervous system (CNS) displaying parallel processes for acute and smouldering neuroinflammation accompanied by text which described the clinical consequences of both processes. Below the graphic there was a statement that smouldering neuroinflammation has been

largely inaccessible as it occurs within the CNS and that one way to impact neuroinflammation is to cross the blood brain barrier and act directly on microglia.

e. Patient Stories and Resources

The Patient Stories and Resources page contained three patient stories that were inspired by real patients. Each patient story included a video, narrated by the patient, in which they described their progression of symptoms and the impact on their life. For each patient there was also a summary of their disease including the time since diagnosis, disability level and information about their disease at different year time points post diagnosis.

In addition to the patient stories, the web page contained five videos of speakers presenting on smouldering neuroinflammation, disability accumulation and PIRA at international congresses. While one of the speaker videos made a general reference to disease modifying treatments, the Panel considered that the content of the videos focussed on the progression of MS and associated disability.

Alleged disguised pre-licence promotion (Clauses 3.1, 3.6 and 11.1)

The Panel noted the complainant's allegation that Sanofi had a "new molecule for nrSPMS recently with a positive opinion from the CHMP and I would assume the MHRA are reviewing for a UK licence. This is the only new treatment for this patient population and therefore the link between their campaign and this new drug is for me explicit and inappropriate". Sanofi submitted that the positive CHMP opinion was adopted by the European Commission on 24 April 2026 with the final EMA approval granted on 23 June 2026. The licenced indication granted was for the treatment of adults with secondary progressive multiple sclerosis without relapses in the last 2 years. The Panel noted that the final European licenced indication was different to the complainant's allegation that the molecule was for nrSPMS. Further the Panel considered that given the post was directed at UK health professionals it was of particular importance that at the time of the complaint Sanofi submitted that an application for a UK licence had not been submitted and it had no planned submission date.

Bearing in mind the broad definition of promotion at Clause 1.17 and particularly noting the very limited evidence before it about tolebrutiniib, in the Panel's view, the smouldering MS campaign (encompassing the LinkedIn post and website) provided information relating to disease and did not appear to directly or indirectly refer to a specific medicine, and was therefore non-promotional. The Panel noted the complainant's allegation that the material was 'disguised promotion, promotion prior to a licence being granted and *promotion to the public*.'. The Panel further noted that Sanofi had been asked to respond to Clauses 3.1 and 11.1. Clause 11.1 appeared in the blue section of the Code and applied to promotion to health professionals and other relevant decision makers. However, Clause 3.1 appeared in the grey section of the Code and was therefore an overarching requirement that applied equally to promotion to health professionals and members of the public. The Panel therefore considered the specific allegation of promotion to the public under Clause 3.1. The Panel considered that the audience was a relevant factor when deciding whether material was promotional. In relation to health professionals the Panel concluded, bearing in mind its comments above, that the complainant had not established that the post and website promoted an unlicensed Sanofi medicine to health professionals and, on that basis, it ruled a **no breach of Clause 11.1**.

In relation to members of the public and the allegation that the material was promotion prior to a licence being granted and promotion to the public the Panel considered the allegation to be that an unlicensed medicine had been promoted to the public. Panel bore in mind its comments above that the material was not promotional in relation to health professionals. Irrespective of its content the Panel noted its comments above about the targeting of the post and clear signposting of all materials. Members of the public were directed via a pop-up box to the Sanofi corporate site. The Panel considered that the material was adequately directed to health professionals and in any event on the information before the Panel the material was not promotional and therefore ruled **no breach of Clause 3.1**.

The Panel noted its ruling above that the LinkedIn post and associated website was not promotional and therefore it followed that it could not be disguised promotion. The Panel ruled **no breach of Clause 3.6**.

Alleged failure to maintain high standards and bringing discredit upon the industry (Clauses 2 and 5.1)

The Panel noted its above rulings of no breach in relation to the allegations of pre-licence and disguised promotion. The Panel considered that the complainant had not established that Sanofi had failed to maintain high standards or that its actions had brought discredit and reduced confidence in the pharmaceutical industry. The Panel ruled **no breach of Clauses 5.1 and 2**.

Complaint received **1 May 2026**

Case completed **25 September 2026**