CASE/0212/06/24

VOLUNTARY ADMISSION BY SANOFI

Voluntary admission about an advertisement for Nexviadyme (avalglucosidase alfa) in a conference brochure

CASE SUMMARY

This case was in relation to an advertisement intended for a pull-up banner being sent in error for inclusion in a conference brochure.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.1	**Failing to include prescribing 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 voluntary admission was made by Sanofi.

As Paragraph 5.14 of the Constitution and Procedure required the Chief Executive to treat a voluntary admission as a complaint, the matter was taken up with Sanofi.

VOLUNTARY ADMISSION

The voluntary admission wording is reproduced below:

> "We are writing to you to report, voluntarily, an issue identified with a Sanofi advertisement in the [UK-based healthcare organisation] conference brochure.
>
> Sanofi takes its obligation under the Code very seriously and is concerned to have identified this, albeit isolated, issue. We can assure you that a full investigation is ongoing, and actions will be taken, with immediate effect, to ensure learning across the organisation to prevent any possible repetition and emphasise the importance of adherence to the ABPI code. However, in the spirit of the code we have decide to inform the PMCPA immediately, while investigations are ongoing.
>
> Sanofi were a sponsor of the 2024 [named organisation] Conference held on [date] and [date] June 2024. This conference was for a specialized group of Healthcare Professionals, i.e. multidisciplinary HCPs working in [named clinical area]. As part of this sponsorship Sanofi had a promotional stand at the conference as well as the ability to have a 1-page advertisement in the conference brochure.

A job bag for the 1-page advertisement, with prescribing information (PI), was approved for the conference brochure (MAT-XU-2400227(v1.0)) and a separate one approved for the pull up banner which specified that the Prescribing Information was available at the stand (MAT-XU-2401007(v1.0)).

However, in error, the approved pull up banner (MAT-XU-2401007(v1.0)) was accidentally sent to the conference organiser, instead of the approved advertisement for the brochure (MAT-XU-2400227(v1.0)). Therefore, the conference brochure advertisement did not have the PI. This was identified by the Sanofi staff during the conference who reached out to the conference organiser immediately. They confirmed that the brochure had been given to most of the attendees and could not be amended. Sanofi can verify the team did have copies of the PI available on the stand.

Sanofi acknowledge this as a breach of Clause 12.1 of the 2021 ABPI code and, while an isolated incident and a genuine human error, recognize this was a breach of high standards i.e., Clause 5.1 of the 2021 ABPI code.

To reiterate, Sanofi does take its obligations under the Code very seriously and is very concerned to have identified this, albeit isolated, issue. We will provide further information upon completion of the full investigation and in line with receipt of formal documentation from the PMCPA."

When writing to Sanofi, the PMCPA asked it to consider the requirements of Clauses 12.1 and 5.1 of the 2021 Code.

SANOFI'S RESPONSE

The response from Sanofi is reproduced below:

"We refer to your letter dated 19th June 24, in which you acknowledged Sanofi's Voluntary Admission in relation to an issue identified with a Sanofi advertisement in the [UK-based healthcare organisation] conference brochure.

Sanofi takes its obligation under the Code very seriously, is concerned to have identified this issue and have conducted a full investigation into the matter at hand.

Issue:

Sanofi were a sponsor of the 2024 [named organisation] Conference held on [date] and [date] June 2024. This conference was for a specialized group of Healthcare Professionals, i.e. multidisciplinary HCPs working in [named clinical area]. As part of this sponsorship Sanofi had a promotional stand at the conference as well as the option to secure a 1-page advertisement in the conference brochure.

A job bag for the 1-page advertisement, with prescribing information (PI), was approved for the conference brochure (MAT-XU-2400227(v1.0)) and, at the same time, a separate one approved for the pull up banner which specified that the Prescribing Information was available at the stand (MAT-XU-2401007(v1.0)).

However, in error, the approved pull up banner (MAT-XU-2401007(v1.0)) was accidentally sent to the conference organiser, instead of the approved advertisement for the brochure (MAT-XU-2400227(v1.0)). Therefore, the conference brochure advertisement did not have the PI. This was identified by the Sanofi staff during the conference who reached out to the conference organiser immediately. They confirmed that the brochure had been given to most of the attendees and could not be amended. Sanofi can verify the team did have copies of the PI available on the stand.

In reporting letter dated 18th June 2024, Sanofi acknowledged this as a breach of Clause 12.1 of the 2021 ABPI code and, while an isolated incident and a genuine human error, recognize this was a breach of high standards i.e., Clause 5.1 of the 2021 ABPI code.

Investigation:

The investigation endeavored to not only focus on the specific issue but also to explore more broadly to confirm that it was not indicative of any systemic issue and identify any actions that should be taken to help prevent re occurrence. Sanofi employees who attended or were involved in preparation for the conference were interviewed, as well as some employees in other parts of the business whose roles include supporting such activities. The Sanofi Compliance team also performed a random check on reported anomalies over the last few years, to see if such an issue had been reported historically.

Outcome:

The outcome of this investigation is as follows:

- Specific issue subject to this voluntary admission:
    - The final 2 items [1-page advertisement, with prescribing information (PI), approved for the conference brochure (MAT-XU-2400227(v1.0)) and the approved pull up banner (MAT-XU-2401007(v1.0)] were sent from the agency to Sanofi [employee 1] with generic codes on them. The [employee 1] did open both to confirm they were the 2 correct items however, in error accidentally sent the incorrect item to [employee 2] who was liaising with the conference organizers.
    - [Employee 2] did not open the item prior to sending it directly on to the conference organisers, due to tight timelines to get the item into the brochure.
    - As this was an advertisement that would be published in the conference brochure (not owned by Sanofi) no hard copy check was performed, and the issue was not identified until the halfway through the conference itself when all brochures had been handed out already to all attendees.
    - The advertisement which, as detailed was actually the approved pull up banner with the statement the Prescribing Information was available on the stand. Sanofi can confirm that this was the case, and PI was available for any HCP who requested it.

- Consideration of if this “is an indication of any systemic issues”?:

- Interviews were conducted with some randomly selected employees, from other parts of the business, who are responsible/support the process regarding sponsorship of third-party meetings and associated materials. It was confirmed that there was no recollection of such an issue previously and that it is rare to have such hard copy materials as many conferences manage materials digitally now. In the rare cases there is hard copy brochures, while it is a challenge to do checks on a publication that is not controlled by Sanofi, it can be possible to get a screenshot in advance, however when attending conference, copies of the brochures are procured for audit purposes.
- [Compliance team] carried out a review of any materials related issues logged in our system since 2021 (post covid) and can confirm that there were no other such issues recorded or identified.

In conclusion, while we acknowledge this breach of clauses 12.1 and 5.1 (as per our original letter), we can ratify Sanofi's initial assessment that this was a genuine, isolated error and not a systemic issue across the company.

Actions taken by Sanofi:

While this has been confirmed as an isolated error, following this investigation, below are the actions that have been initiated and currently ongoing:

- The local Working Instruction on Sponsorship of Third-Party meetings is in the process of being updated to add more clarity for the need to ensure that materials are correctly labelled and double checked prior to sending to conference organiser.
- The supporting document to our local materials management process is being updated to add expectation to work with third party organisers to get a printer's proof or image of the sample copies of the items in brochures as soon as available to support ability to do checks in advance of the conference.
- This scenario will be shared widely across the organisation with the above-mentioned changes highlighted to support learning to continually improve. This will take place over the rest of Q3 2024 at relevant team meetings and this case will form part of the learning programme for our upcoming September's Code forum.

To reiterate, Sanofi does take its obligations under the Code very seriously and is concerned to have identified this, albeit isolated, issue. The above-mentioned actions will support learning across the organisation to prevent possible recurrence and emphasize the importance of adherence to the ABPI code this issue."

PANEL RULING

The Panel noted Sanofi had sponsored a conference at which it had a promotional stand and a one-page advertisement in the conference brochure.

In its voluntary admission, Sanofi stated that the advertisement for Nexviadyme (avalglucosidase alfa) intended for its pull-up banner stand had been sent in error for inclusion in the conference brochure. The advertisement included the claim "MAKE THE NEX MOVE TO

NEXVIADYME For your appropriate patients with Pompe disease" and the product's indication. The advertisement referred to the availability of prescribing information at the stand.

Clause 12.1 of the 2021 Code required that prescribing information must form part of the promotional material and must not be separate from it. The supplementary information to Clause 12.1, for exhibitions, allowed for prescribing information to be available at the company stand, provided this was referred to on the posters or panels.

The Panel noted that the advertisement printed in the conference brochure did not, itself, include prescribing information and considered it did not meet the requirements of Clause 12.1. A **breach of Clause 12.1** was ruled.

The Panel took account of the lack of oversight and omission of prescribing information. The Panel considered that prescribing information was an important contributor to patient safety. In the Panel's view, the circumstances of the case were such that Sanofi had failed to maintain high standards and a **breach of Clause 5.1** was ruled.

Complaint received **18 June 2024**

Case completed **18 March 2025**