CASE AUTH/3455/1/21

COMPLAINANT v SANOFI

Promotion of Toujeo Double Star (insulin glargine)

An anonymous, non-contactable complainant complained about the conduct of a Sanofi representative at a virtual meeting to promote Toujeo (insulin glargine solution (300 units/ml) for injection in a pre-filled pen).

Toujeo was indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years. Toujeo was available in two pen sizes: a SoloStar pen (contained 1.5 ml of solution for injection, equivalent to 450 units) and a DoubleStar pen (contained 3 ml of solution for injection, equivalent to 900 units).

The complainant alleged that the representative claimed that using DoubleStar resulted in fewer prescriptions and when he/she queried why that was the case and suggested that it was erroneous and misleading, the representative simply moved on. There was also a suggestion that fewer prescriptions would result in a time and cost saving. The complainant stated that he/she repeatedly pointed out that theclaim was incorrect (fewer pens, not fewer prescriptions), but this was not acknowledged.

The representative went on to discuss a health professional programme within the same presentation which the complainant alleged was inappropriate. The programme was discussed to further promote Toujeo ie by using Toujeo health professionals would be invited to a remote insulin management meeting. A copy of a slide which appeared to refer to a programme named PRIME (providing remote insulin management & education) was provided.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that it had been discussed internally and decided that the claim 'fewer prescriptions' in relation to the use of the Toujeo DoubleStar pen within the Toujeo promotional slide deck (ref MAT-GB-2004667 (V1.0)) could not be substantiated. In error, the slide deck including the claim at issue was approved on 13 November 2020. The Panel noted Sanofi's submission that the error was identified and flagged internally on 25 November 2020 and a revised slide deck was issued on 4 December 2020 to replace the inaccurate version.

The Panel considered that the claim that Toujeo DoubleStar offered 'fewer prescriptions' in the presentation certified on 13 November and available until 4 December 2020 was misleading and incapable of substantiation and high standards had not been maintained; breaches of the Code were ruled as acknowledged by Sanofi.

The Panel noted Sanofi's submission that whilst the briefing for representatives stated the intended audience and an overview of what was going to be covered in the slide

deck, it did not contain any guidance on how to discuss the claim of 'fewer prescriptions' because it was not intended to be included in the slide deck. The Panel further noted Sanofi's submission that, overall, briefing for this slide deck should have been more detailed and matched the associated material. The Panel did not consider that the briefing was sufficiently detailed and a breach of the Code was ruled as acknowledged by Sanofi.

In relation to the allegation that a health professional programme (PRIME) had been inappropriately discussed in the presentation, implying that if Toujeo was used those health professionals would be invited to a remote insulin management meeting, the Panel noted Sanofi's submission that PRIME (Providing Remote Insulin Management and Education) was a promotional educational programme intended for all health professionals (regardless of their prescribing habits) involved in treating patients with insulin, to help them better manage their patients remotely in the current climate [pandemic].

The Panel noted that, according to the briefing (ref MAT-GB-2004668 (V1.0)) in relation to the Toujeo promotional speaker slide kit (ref MAT-GB-2004667 (V1.0)), the slide kit was only to be used if it met one or both of the following scenarios: following a recent clinical presentation on Toujeo (within 1 month) and/or where the audience included health professionals who were known prescribers of Toujeo and were aware of the clinical data for Toujeo.

The Panel, however, noted Sanofi's submission that only one slide out of fifteen, in the Toujeo promotional speaker slide kit, included a brief summary of the PRIME programme as an example of how Sanofi was trying to support its customers during the pandemic and that the content of that slide, along with the briefing for the entire deck, contained no language suggestive of any intent to link the offering with prescribing of any Sanofi product, including Toujeo. The slide described PRIME as a learning programme intended for primary and intermediate care health professionals to effectively and confidently manage patients on insulin remotely. The Panel further noted Sanofi's submission that it interviewed a selection of members of the diabetes sales force and did not find any evidence that PRIME was discussed in any way as an inducement to prescribe a Sanofi medicine and no concerns had been raised to representatives in any meetings.

The Panel noted that the materials and associated content for the PRIME programme were not before it and were not the subject of the complaint. The Panel did not consider that the complainant had provided evidence to establish that the slide summarising the PRIME programme, as part of a promotional presentation, was inappropriate, as alleged, such that it was an inducement to prescribe, supply, administer, recommend, buy or sell any medicine; no breaches of the Code were ruled including Clause 2.

An anonymous, non-contactable complainant complained about the conduct of a Sanofi representative at a virtual meeting to promote Toujeo (insulin glargine solution (300 units/ml) for injection in a pre-filled pen).

Toujeo was indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years. Toujeo was available in two pen sizes: a SoloStar pen (contained 1.5 ml of solution for injection, equivalent to 450 units) and a DoubleStar pen (contained 3 ml of solution for injection, equivalent to 900 units).

COMPLAINT

The complainant stated that a few slides into the representative's presentation on Toujeo, the representative claimed that using DoubleStar resulted in fewer prescriptions.

The complainant explained that when he/she queried why that was the case and suggested that it was erroneous and very misleading, the representative simply moved on. There was also a suggestion that fewer prescriptions would result in a time and cost saving. The complainant stated that he/she repeatedly pointed out that the claim was incorrect (fewer pens, not fewer prescriptions), but this was not acknowledged. The complainant provided a copy of what appeared to be a slide with the heading:

> '**Toujeo DoubleStar-**the highest unit capacity basal insulin pen on the market[1-5]
> Offering convenience for your patients with a long-lasting pen and fewer prescriptions'

The complainant stated that the representative went on to discuss a patient programme and health professional programme within the same presentation which he/she considered was completely inappropriate. The complainant considered that both programs were discussed to further promote Toujeo ie by using Toujeo health professionals would be able to access a patient support program and be invited to a remote insulin management meeting. A copy of a slide which appeared to refer to a programme named PRIME (providing remote insulin management & education) was provided.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 7.2, 7.4 and 9.1 of the Code in relation to the allegations regarding the claim 'fewer prescriptions' and the requirements of Clauses 18, 9.1 and 2 in relation to the allegations about the health professional programme and health professionals prescribing Toujeo being invited to a remote insulin management meeting. Sanofi was also asked to bear in mind the provisions of Clause 15.9 of the Code.

RESPONSE

1 Claim 'fewer prescriptions' with DoubleStar

Sanofi stated that the Toujeo promotional slide deck in question (ref MAT-GB-2004667 (V1.0)) was entitled 'How can we effectively support our patients during this time?' and had been approved to be presented during Sanofi organised promotional meetings to an audience of health professionals, as defined in the associated brief.

The claim regarding 'fewer prescriptions' had been discussed internally during development and it had been agreed mutually, by all stakeholders, that it could not be substantiated. Unfortunately, when the deck was approved for use on 13 November 2020 it contained the claim. Sanofi submitted that this was a genuine human error, as there was no intention to use that claim in promotional material for Toujeo Doublestar. It was identified and flagged internally on 25 November 2020 and an action plan drawn up to address the error in the slide deck. The revised slide deck was re-issued on 4 December 2020, replacing the inaccurate version.

Sanofi noted that the complainant had provided little evidence of the date or time of the meeting and that the burden of providing evidence sat with the complainant. Sanofi had interviewed a selection of members of the diabetes field sales force to investigate the matter further. Nothing

had been identified from those interviewed to suggest an attendee of a virtual meeting had raised concerns about the claim 'fewer prescriptions'. Sanofi stated that it therefore had not found any evidence to suggest a breach of high standards in relation to the activities of Sanofi employees presenting at the meetings.

Sanofi acknowledged that, while the inclusion of the claim of 'fewer prescriptions' in relation to use of the Doublestar pen in the first version of the deck was a genuine human error, the slide deck did have that claim on it for a period of time. Sanofi therefore accepted breaches of Clauses 7.2 and 7.4. While the error was identified and resolved by 4 December, Sanofi accepted that there were six working days before the changes took place and it agreed that that was an unintentional breach of high standards (9.1).

2 Health professional programme and link to prescribing

Sanofi noted that the complainant was concerned that the health professional educational programme (PRIME) had been inappropriately covered in a promotional presentation. The complainant alleged that discussion of the programme was to further promote Toujeo, and that by using Toujeo health professionals would be invited to a remote insulin management meeting.

Sanofi explained that PRIME was a promotional educational programme intended for all health professionals (regardless of their prescribing habits) involved in treating patients with insulin, to help them better manage their patients remotely in the current climate. It was planned to be officially launched in the first quarter of 2021. Only one slide summary (out of 15 slides) on the programme was included in the presentation as a brief overview of an example of how Sanofi was trying to support its customers during the pandemic. The contents on the slide, along with the briefing for the entire deck, contained no language to suggest any intent to link the offering with prescribing of any Sanofi product, including Toujeo.

Sanofi again noted that little evidence of the date or time of the meeting had been provided by the complainant, and that the burden of providing evidence sat with the complainant. Sanofi had interviewed a selection of members of the diabetes field sales force to investigate the matter further and had found no evidence that PRIME was discussed in any way as an inducement to prescribe and no concerns were raised to Sanofi representatives in any meetings at which they presented.

Sanofi therefore refuted breaches of Clauses 2, 9.1, or 18 with respect to the brief coverage of the PRIME programme in the slide deck.

3. Briefing materials

Sanofi stated that the brief clearly stated the intended audience for this type of meeting and gave a clear overview of what would be covered in the slide deck. Sanofi noted during its investigation that the briefing did not contain any guidance on how to discuss the claim of 'fewer prescriptions'. This was because the claim was not intended to be included in the deck and therefore the briefing was consistent with that intent. However, Sanofi acknowledged that overall, the slide deck briefing should have been more detailed and matched the associated material. Sanofi therefore accepted the breach of Clause 15.9.

4. Information about Toujeo Coach patient support programme and associated instructions

Following assessment of Sanofi's response in relation to information about the Toujeo Coach patient support programme and associated instructions, the case preparation manager decided that there was no prima facie case to answer with regard to the allegation that it was inappropriate to refer to the patient programme within the presentation. The case preparation manager noted that it was not necessarily a breach of the Code to do this and it was for the complainant to show on the balance of probabilities that there had been a breach of the Code. The case preparation manger informed Sanofi that this particular allegation would not be considered by the Panel.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority stated that anonymous complaints would be accepted but that like all other complaints, the complainant had the burden of proving his/ her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

The Panel noted Sanofi's submission that it had been discussed internally and decided that the claim 'fewer prescriptions' in relation to the use of the Toujeo DoubleStar pen within the Toujeo promotional slide deck (ref MAT-GB-2004667 (V1.0)) could not be substantiated. The Panel further noted Sanofi's submission, however, that in error, the slide deck including the claim at issue was approved on 13 November 2020. The Panel noted Sanofi's submission that the error was identified and flagged internally on 25 November 2020 and a revised slide deck was re-issued on 4 December 2020 to replace the inaccurate version.

The Panel considered that the claim that Toujeo DoubleStar offered 'fewer prescriptions' which was included in the presentation certified on 13 November and available until 4 December 2020 was misleading and incapable of substantiation; a breach of Clauses 7.2 and 7.4 was ruled as acknowledged by Sanofi.

The Panel further noted the length of time between Sanofi identifying the error and withdrawing the material containing the claim at issue. The Panel considered that Sanofi had failed to maintain high standards in that regard and ruled a breach of Clause 9.1 as acknowledged by Sanofi.

The Panel noted that Clause 15.9 of the Code required companies to prepare detailed briefing material for representatives on the technical aspects of each medicine which they would promote. The supplementary information to Clause 15.9 stated that the briefing material referred to in the Clause consisted of both the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted. The Panel noted Sanofi's submission that whilst the briefing stated the intended audience, and an overview of what was going to be covered in the slide deck, it did not contain any guidance on how to discuss the claim of 'fewer prescriptions' because it was not intended to be included in the slide deck. The Panel further noted Sanofi's submission that, overall, briefing for this slide deck should have been more detailed and matched the associated material. The Panel did not consider that the briefing was sufficiently detailed as required by Clause 15.9 and a breach was ruled as acknowledged by Sanofi.

In relation to the allegation that a health professional programme (PRIME) had been inappropriately discussed in the presentation, implying that if Toujeo was used those health

professionals would be invited to a remote insulin management meeting, the Panel noted Sanofi's submission that PRIME (Providing Remote Insulin Management and Education) was a promotional educational programme intended for all health professionals (regardless of their prescribing habits) involved in treating patients with insulin, to help them better manage their patients remotely in the current climate [pandemic].

Clause 18.1 stated that no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3.

The Panel noted that, according to the briefing (ref MAT-GB-2004668 (V1.0)) in relation to the Toujeo promotional speaker slide kit (ref MAT-GB-2004667 (V1.0)), the slide kit was only to be used if it met one or both of the following scenarios: following a recent clinical presentation on Toujeo (within 1 month) and/or where the audience included health professionals who were known prescribers of Toujeo and were aware of the clinical data for Toujeo.

The Panel, however, noted Sanofi's submission that only one slide out of fifteen, in the Toujeo promotional speaker slide kit, included a brief summary of the PRIME programme as an example of how Sanofi was trying to support its customers during the pandemic and that the content of that slide, along with the briefing for the entire deck, contained no language suggestive of any intent to link the offering with prescribing of any Sanofi product, including Toujeo. The slide described PRIME as a learning programme intended for primary and intermediate care health professionals to effectively and confidently manage patients on insulin remotely. The Panel further noted Sanofi's submission that it interviewed a selection of members of the diabetes sales force and did not find any evidence that PRIME was discussed in any way as an inducement to prescribe a Sanofi medicine and no concerns had been raised to representatives in any meetings.

The Panel noted that the materials and associated content for the PRIME programme were not before it and were not the subject of the complaint. The Panel did not consider that the complainant had provided evidence to establish that the slide summarising the PRIME programme, as part of a promotional presentation, was inappropriate, as alleged, such that it was an inducement to prescribe, supply, administer, recommend, buy or sell any medicine; no breach of Clause 18.1 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2 in relation to this matter.

Complaint received **20 January 2021**

Case completed **19 August 2021**