

CASE AUTH/3468/2/21

ANONYMOUS EMPLOYEE v SANOFI

Promotion of Toujeo

An anonymous, non-contactable complainant who described themselves as a Sanofi employee complained about an email that had been sent to the salesforce headed 'Toujeo news – Patient material & Digital campaign'.

Toujeo (insulin glargine solution (300 units/ml solution for injection in a pre-filled pen) was indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

The email at issue began by referring to the availability of the Toujeo SoloStar and DoubleStar printed booklets and how they could be ordered. Then beneath the heading, 'On another note', referred to digital campaigns run by Sanofi to complement the efforts in the field. The email referred to three campaigns for health professionals and that representatives were made aware of one of the campaigns in particular should any health professionals reach out after seeing it. The representatives were also informed that the content of the email was for internal awareness only and not to be shared externally. The email then included some screenshots to show representatives the promotional messaging within one of the digital campaigns.

The complainant stated that in his/her view, a patient support update should not be included in an email which also included promotional messaging as that could be interpreted that employees should use patient materials to promote their products. The complainant was also concerned that promotional messaging and content were rife within the email and he/she could not see any form of approval code.

The complainant submitted that he/she did not feel comfortable raising the matter with any of the senior leaders within his/her business unit as he/she considered that that would impact on his/her career.

The detailed response from Sanofi is given below.

The Panel considered that whilst patient materials must not constitute promotion of a prescription only medicine to the public, the Code did not prohibit referring to patient materials in promotional material for health professionals. The availability and content of the patient materials might be a factor for a health professional in deciding between similarly appropriate treatments for a condition. It was not necessarily a breach of the Code to refer to patient materials in communications to representatives which also referred to promotional campaigns/messaging.

In relation to the allegation in this case, the Panel considered that referring to the patient materials and the promotion of medicines in the same email was not in itself

inappropriate as alleged. It therefore did not consider that Sanofi had failed to maintain high standards in this regard and no breach of the Code was ruled.

The Panel considered that announcing the availability of the patient materials and how to order them and then details of the promotional digital campaigns to be run should any health professionals reach out after seeing them would be seen as instructions to representatives regarding the promotion of the medicines. The Panel thus considered that the email should have been certified as briefing material. The failure to do so was ruled in breach of the Code including that high standards had not been maintained as acknowledged by Sanofi.

An anonymous, non-contactable complainant who described themselves as a Sanofi employee complained about an email that had been sent to the salesforce headed 'Toujeo news – Patient material & Digital campaign'. A copy of the email was provided.

Toujeo (insulin glargine solution (300 units/ml solution for injection in a pre-filled pen) was indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

The email at issue began by referring to the availability of the Toujeo SoloStar and DoubleStar printed booklets and how they could be ordered. Then beneath the heading, 'On another note', referred to digital campaigns run by Sanofi to complement the efforts in the field. The email referred to three campaigns for health professionals, one run earlier in the year (Toujeo Paediatric M3 digital campaign), a second (BRIGHT Digital campaign) to run for a month from the date of the email, and a third (Toujeo Coach Digital campaign) that would be made live following the BRIGHT campaign above to those health professionals who had engaged with it. Details of the platforms on which the second and third campaign would be run was provided. According to the email, representatives were made aware of the BRIGHT campaign should any health professionals reach out after seeing it. The representatives were also informed that the content of the email was for internal awareness only and not to be shared externally. The email then included some screenshots to show the representatives the promotional messaging within the BRIGHT digital campaign.

COMPLAINT

The complainant was concerned about how the email could be construed and noted that although it began with an update on patient support materials, it very quickly became promotional in that it discussed a new digital campaign, with screenshots of the campaign and promotional messaging.

The complainant stated that in his/her view, a patient support update should not be included in an email which also included promotional messaging as that could be interpreted that employees should use patient materials to promote their products. The complainant was also concerned that promotional messaging and content were rife within the email and he/she could not see any form of approval code.

The complainant submitted that he/she did not feel comfortable raising the matter with any of the senior leaders within his/her business unit as he/she considered that that would impact on his/her career.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 9.1, 14.1 and 15.9 of the Code.

RESPONSE

Sanofi submitted that it was disappointed that the matter was not raised by the complainant internally as the company had a strong focus on compliance and open discussion. All colleagues were encouraged to raise matters of concern to discuss, in team meetings or in confidence, with members of their immediate management, division leadership, or medical/compliance teams without fear of it impacting their careers.

Sanofi submitted that the email in question was intended to inform representatives of the availability of patient support materials and provide an awareness of some of the promotional digital campaigns (an attached screenshot example was provided) that the head office team had planned in the year. Patient materials were in the scope of the Code and Sanofi did not believe it was a breach of the Code to refer to promotional campaigns or messaging in the same email where representatives were informed of the availability of patient support materials. There was also no call to use the patient materials in an inappropriate way. Sanofi therefore refuted a breach of Clause 9.1 with respect to mention of patient materials and promotional messaging in the same email.

Sanofi submitted that with regard to the digital campaigns referred to in the email, none of them required the involvement of representatives and there were no plans or actions for field force engagement. Therefore, those campaigns were only communicated in the email so representatives remained well informed on business activities relevant to their environment. Finally, the messages seen in the screenshot in the email were also captured in many previous promotional campaigns and representatives had been trained on those messages. Since there was no call to action, the email was not considered to be briefing material and therefore it was not certified. However, upon careful consideration as to how the contents of the email could have been interpreted, Sanofi acknowledged that it should have been clearer on what the information meant for representatives and certified as a briefing document. Sanofi, therefore, accepted that, on this occasion, it had not maintained its usual very high standards and accepted breaches of Clauses 9.1, 14.1 and 15.9.

PANEL RULING

The Panel considered it would have been helpful if the complainant had raised his/her concerns directly with the company. It understood, however, that employees did not always feel comfortable to do so. Companies should make every effort to encourage employees to raise concerns.

The Panel considered that whilst patient materials must not constitute promotion of a prescription only medicine to the public, the Code did not prohibit referring to patient materials in promotional material for health professionals. The availability and content of the patient materials might be a factor for a health professional in deciding between similarly appropriate treatments for a condition. It was not necessarily a breach of the Code to refer to patient materials in communications to representatives which also referred to promotional campaigns/messaging.

In relation to the allegation in this case, the Panel considered that referring to the patient materials and the promotion of medicines in the same email was not in itself inappropriate as alleged. It therefore did not consider that Sanofi had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

The Panel noted that Clause 15.9 stated, *inter alia*, that companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote which must comply with the relevant requirements of the Code and in particular, was subject to the certification requirements of Clause 14. The supplementary information stated that the detailed briefing material referred to in Clause 15.9 consisted of both the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel considered that announcing the availability of the patient materials and how to order them and then details of the promotional digital campaigns to be run should any health professionals reach out after seeing them would be seen as instructions regarding the promotion of the medicines as referred to in the supplementary information to Clause 15.9. The Panel thus considered that the email should have been certified. The failure to do so was ruled in breach of Clause 14.1 of the Code as acknowledged by Sanofi. The Panel considered that high standards had not been maintained in this regard and a breach of Clause 9.1 was ruled as acknowledged by Sanofi.

The Panel noted that Clause 15.9 further stated that briefing material for representatives must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

Whilst the Panel noted Sanofi's acknowledgement that the email should have been clearer about what the information meant for representatives, it did not consider that the email advocated any action which would be likely to lead to a breach of the Code. It had, however, not been certified as referred to in Clause 15.9 and therefore did not comply with that relevant requirement of the Code as required by Clause 15.9. The Panel therefore ruled a breach of Clause 15.9 as acknowledged by Sanofi.

Complaint received **3 February 2021**

Case completed **9 July 2021**