CASE AUTH/3454/1/21 *NO BREACH OF THE CODE*

EMPLOYEE v SANOFI

Briefing materials for representatives

An anonymous, non-contactable complainant, who described themselves as a Sanofi representative, complained about briefing materials for Toujeo Coach – a patient support programme for adults prescribed Toujeo.

Toujeo (insulin glargine solution (300 units/ml) for injection in a pre-filled pen) was indicated for the treatment of diabetes mellitus.

The complainant noted that he/she had raised concerns with his/her manager and the marketing department but nothing had changed. The complainant stated that an email was sent regarding an approved invitation for a Toujeo Coach webinar aimed at health professionals, but a follow-up email informed the representatives of an error using the invitation. The complainant stated that rather than correcting the error and approving the content, the representatives were asked to copy and paste the email invitation and send it themselves. The complainant submitted that he/she had raised concerns that copying and pasting an approved email invitation might lead to errors and data being missed – none of those concerns were listened to.

The complainant stated that as part of the same email trail, representatives were asked to track their emails and send in how many people they had sent the email to. This might have led to representatives feeling pressurised to send the email to as many people as possible whether compliant or not. The complainant further noted that in one case a named colleague had possibly sent uncompliant reminder emails.

Finally, the complainant expressed his/her concerns about the culture that the above promoted and how the issues he/she had raised had been ignored.

The detailed response from Sanofi is given below.

The Panel noted that the representatives were provided with a certified email invitation and associated certified briefing document which advised representatives to open the email attached and send it directly from their professional mailbox. The Panel noted Sanofi's submission that the only amendments permissible were the names and email addresses, and that the briefing did not allow the content or title of the original email to be amended. The briefing stated 'if you cannot reuse the invite multiple times, simply copy and paste the content which should be identical each time. Do not amend/edit the content or title of the original email'.

The Panel considered that the instruction to copy and paste the contents of the email if the template could not be sent directly was consistent with the certified email briefing. The Panel did not have any evidence before it that the briefing document advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the

Code or that 'copying and pasting' the certified content of the email template by any representative had led to errors or that data from the original, certified email content was missed as alleged. The Panel thus ruled no breaches of the Code.

The Panel noted Sanofi's submission that the head office organiser requested an indication of the number of invites sent by the representatives to health professionals to gauge the level of interest and to anticipate the potential number of attendees for each event which in the Panel's view was not unreasonable. The Panel noted Sanofi's submission that representatives did not have any associated contact metrics attached to the activity; there was no evidence of a direction or pressuring to achieve a target number of responses.

The Panel did not consider there was evidence that being asked to track their emails and notify the company would have pressurised representatives to send the email to as many people as possible, whether compliant or not as alleged. The briefing included detailed compulsory criteria regarding which health professionals could be invited to the webinar. The Panel did not consider that the request advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code and no breach was ruled.

The Panel further noted that the complainant referred to an email, in which a named representative stated that he/she had sent reminder emails to approximately 10 of the 20 recipients that had been sent the original email invitation; the complainant alleged this might have been uncompliant. The Panel noted Sanofi's submission that the named representative had no recollection of the email highlighted by the complainant and that there was no record in its customer relationship management (CRM) system of the representative sending reminder emails. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the representative had not maintained a high standard of ethical conduct based on his/her allegations. The Panel, based on the evidence before it, ruled no breach of the Code.

The Panel noted its comments and rulings above, and on the evidence before it, the Panel did not consider that Sanofi had failed to maintain high standards and no breach of the Code was ruled.

An anonymous, non-contactable complainant, who described themselves as a Sanofi representative, complained about briefing materials for Toujeo Coach – a patient support programme for adults prescribed Toujeo.

Toujeo (insulin glargine solution (300 units/ml) 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.

COMPLAINT

The complainant noted that he/she had raised concerns with his/her manager and the marketing department but in each case nothing had changed. The complainant stated that an email was sent regarding an approved invitation for a Toujeo Coach webinar aimed at health professionals. That all seemed fine, but a follow-up email informed the representatives of an error using the invitation. Rather than correcting the error and approving the content, the representatives were asked to copy and paste the email invitation and send it themselves. The complainant submitted that he/she had raised concerns that copying and pasting an approved email invitation might lead to errors and data being missed – none of those concerns were listened to and he/she was told to get on with it.

The complainant submitted that as part of the same email trail, representatives were asked to track their emails and send in how many people they had sent the email to. The complainant considered that that might have led to representatives feeling pressurised to send the email to as many people as possible whether compliant or not. The complainant further noted that representatives had sent in their responses and in one case a named colleague had possibly sent uncompliant reminder emails on the subject. The complainant attached emails that had been internally circulated on the above matters.

Finally, the complainant expressed his/her concerns about the culture that the above promoted and how the issues he/she had raised had been ignored.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 15.2, 15.9, 14.1 and 9.1 of the Code.

RESPONSE

Sanofi was surprised and disappointed that such a complaint had been made, as the company was committed to maintaining high standards in relation to all internal and external communications and in complying with the Code in all relevant activities.

By way of background, Sanofi stated that in 2020 its diabetes franchise identified renewed interest from health professionals in Toujeo Coach, a patient support programme which aimed to support patients' prescribed Toujeo in its use.

In view of health professionals' questions on how the programme could support their patients in the current Covid environment, two webinars were set up in June 2020 to provide further information. Attendance levels at those meetings had confirmed their potential value to health professionals and as a result, a further two webinars were planned for November 2020. Representatives were provided with an approved email and an accompanying briefing (copies attached).

Sanofi noted that the complainant had provided little evidence to substantiate his/her complaint, and that the burden of providing evidence sat with the complainant. Sanofi had interviewed relevant personnel within the diabetes marketing team and a selection of members of the diabetes field force, including sales managers (being mindful of the anonymous nature of the complainant and the need to maintain that anonymity) to investigate the matter further.

Sanofi stated that the diabetes representatives were provided with a certified email invitation (ref MAT-GB-2004596 v1.0) and an associated, certified briefing document (ref MAT-GB-2004594 v1.0). The latter instructed on the appropriate audience for the webinars and how to use the template email provided to invite health professionals. The briefing advised that the content and subject line could be copied and pasted into an Outlook message, but the only content amendments permissible were to add the appropriate names and email addresses before sending. This was in line with PMCPA website Q&A guidance on certification of the final form of such templates (copy provided). Before the email was sent to the sales team, the owner of the material had confirmed that all linked content in the email was working as had been certified. The material was also tested to ensure that when copied/pasted and sent, the links would still function in the same way as when certified. That was the only certified invite email provided to the sales force for the purpose.

After internal distribution, the owner of the material received a query from a representative which advised of a difficulty with a greyed out 'send button' when attempting to use the email template.

The enquirer was advised to use 'copying and pasting' to resolve that, an instruction which was consistent with the original certified briefing document for using the email template. That was also re-communicated to all other representatives in case there were others with a similar query.

Guidance on the PMCPA website (Q&A screenshot provided) advised that if an invitation was promotional, the addition of a name and/or date was not part of the promotional materials and could be added after certification. This was consistent with the use of a certified template, such as that provided to Sanofi's representatives.

Sanofi refuted breaches of Clauses 14.1 and 15.9 in relation to the review, approval and briefing of the materials. No evidence had been submitted to substantiate a breach of those clauses, and in investigating the matter further, the email template to be used had been appropriately certified, and the representatives had been appropriately briefed using certified materials.

Sanofi stated that no evidence had been identified of a culture whereby representatives were pressurised to send invitations to inappropriate health professionals. Representatives did not have any associated contact metrics attached to the activity and Sanofi's interviews had consistently, and without exception, shown that they were, and still were, sensitive to the workplace challenges faced by NHS customers in the current climate. Sanofi explained that the webinar organiser had requested an indication of the number of invitations sent by the representatives in order to gauge the level of interest and to anticipate the potential number of health professionals for each event. There was no performance tracking of the level of the number of attendees generated by individual representatives, nor a target number of invitees to be achieved, nor any evidence of a direction or pressuring to achieve a target number of responses.

Sanofi submitted that the sales managers interviewed reiterated that the company's external interactions were focussed on where the right content at the right time added value to that particular health professional. Those managers consistently confirmed their own confidence in raising any queries or concerns with their colleagues and stated that they would be comfortable to escalate internally to managers and/or the compliance team if they were unhappy with any responses received.

Sanofi submitted that no evidence had been submitted to substantiate the complaint that high standards were not maintained. Sanofi had found no evidence to show that any of the field teams acted, or were directed to act, outside the certified briefing received for the webinars, nor that high standards had not been maintained at all times.

Sanofi refuted breaches of Clauses 15.2 or 9.1.

Overall, Sanofi noted the lack of evidence provided by the anonymous, non-contactable complainant and that it had not identified any evidence to support his/her allegations.

In response to a request for further information by the Panel, with regard to the alleged 'uncompliant reminder emails', Sanofi re-emphasised that its original investigation included interviews of relevant personnel, taking steps to maintain the anonymity of the complainant. The representative named by the complainant was interviewed as part of this investigation. When questioned, the named representative recalled the webinars in question, but little of the detail relating to materials for this specific event, due to the time that had passed since the event in question; he/she could not recall sending reminder emails.

Sanofi had now had the opportunity to speak to and show the named representative the screenshot of the specific content which referred to the reminder emails, and the representative had no recollection of sending this email. Sanofi submitted that the lack of details showing date or time sent made it difficult for Sanofi to track further and, in addition, Sanofi staff mailboxes were subject to an email retention policy of 90 days when the November 2020 Toujeo Coach Q&A webinars took place. Sanofi submitted it had additionally looked at the named representative's customer call records, as recorded in the Sanofi customer relationship management (CRM) system and had not been able to identify evidence of the sending of follow-up customer invite emails for these events.

Sanofi stated it could confirm that there were no 'follow-up' invites or 'reminder' emails certified relating to these November webinars, however without further evidence from the complainant to support this element of the complaint, Sanofi was unable to conclude that the named representative had sent 'uncompliant reminder emails'.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. Like all complaints, anonymous complaints were judged on the evidence provided. The complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that the representatives were provided with a certified email invitation and associated certified briefing document which advised representatives to open the outlook email attached and send it directly from their professional mailbox. The Panel noted Sanofi's submission that the only amendments permissible were the names and email addresses, and that the briefing did not allow the content or title of the original email to be amended.

The briefing stated 'if you cannot reuse the invite multiple times, simply copy and paste the content which should be identical each time. **Do not amend/edit the content or title of the original email**'.

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. Briefing material must comply with the relevant requirements of the Code and, in particular, was subject to the certification requirements of Clause 14. Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

The Panel considered that the instruction to copy and paste the contents of the email if the template could not be sent directly was consistent with the certified email briefing. The Panel did not have any evidence before it that the briefing document advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code or that 'copying and pasting' the certified content of the email template by any representative had led to errors or that data from the original, certified email content was missed as alleged. The Panel thus ruled no breach of Clauses 14.1 and 15.9.

The Panel noted Sanofi's submission that the head office organiser requested an indication of the number of invites sent by the representatives to health professionals to gauge the level of interest and to anticipate the potential number of attendees for each event which in the Panel's view was not unreasonable. The Panel noted Sanofi's submission that representatives did not have any associated contact metrics attached to the activity; there was no performance tracking of the level of the number of attendees generated by individual representatives, nor a target number of invitees

to be achieved, nor any evidence of a direction or pressuring to achieve a target number of responses.

The Panel did not consider there was evidence that being asked to track their emails and notify the company would have pressurised representatives to send the email to as many people as possible, whether compliant or not as alleged. The briefing document included detailed compulsory criteria regarding which health professionals could be invited to the webinar. The Panel did not consider that the request advocated, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code and no breach of Clause 15.9 was ruled.

The Panel further noted that the complainant referred to an email, in which a named representative stated that he/she had sent reminder emails to approximately 10 of the 20 recipients that had been sent the original email invitation; the complainant alleged this might have been uncompliant. The Panel noted Sanofi's submission that the named representative had no recollection of the email highlighted by the complainant and that there was no record in its customer relationship management (CRM) system of the representative sending reminder emails; Sanofi submitted that the lack of details showing date or time sent made it difficult to track down further and that staff mailboxes were subject to an email retention policy of 90 days. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the representative had not maintained a high standard of ethical conduct based on his/her allegations. The Panel, based on the evidence before it, ruled no breach of Clause 15.2.

The Panel noted its comments and rulings above, and on the evidence before it, the Panel did not consider that Sanofi had failed to maintain high standards and no breach of Clause 9.1 was ruled.

Complaint received **20 January 2021**

Case completed **8 September 2021**