CASE AUTH/3026/3/18

ANONYMOUS EMPLOYEE v SANOFI

Promotion of Toujeo and Lantus

An anonymous, non-contactable complainant who described themselves as a Sanofi employee complained about a manager's briefing with regard to the promotion of Lantus (insulin glargine 100 units/mL) and Toujeo (insulin glargine 300 units/mL). Both medicines were used in diabetes mellitus.

The complainant provided a copy of an email sent from a manager to his/her team of representatives. The email chain included a regional head who responded and endorsed the email. The complainant alleged that Sanofi acknowledged the manager's success but turned a blind eye as to how it was achieved, as his/her results were significantly higher compared with other colleagues.

The complainant alleged that the manager actively encouraged representatives to have detailed discussions around patients with health professionals thereby resulting in audits and identification of patient groups. This was documented as best practice and included:

1 **Patients to be identified and started on Toujeo via other ways and means of the agreed policy.**

2 **Several mentions of adverse reactions with Lantus.**

3 **Discussions around off-licence, twice daily Lantus.**

4 **The Toujeo coach service for patients was being used and tracked by the representative.**

The detailed response from Sanofi is given below.

The Panel noted the complainant's allegation that the manager was encouraging identification of patients for Toujeo outside an agreed policy. (Sanofi submitted the policy was an NHS protocol provided by consultants to general practitioners). The Panel noted that within the email two representatives made reference to the agreed policy being a barrier in certain circumstances. The Code did not state that a medicine must be promoted within the terms of local, regional or national guidelines. However, the Code required information claims and comparisons to be, *inter alia*, accurate, balanced, fair and not inconsistent with the particulars in its summary of product characteristics (SPC). The Panel did not consider that the complainant had provided any evidence which demonstrated that any of Sanofi's representatives had promoted Toujeo outside the terms of its marketing authorisation or that the email in question advocated such use and therefore no breach of the Code was ruled.

The Panel noted the complainant's statement that 'Several mentions of adverse reactions with Lantus' were documented. The Panel noted that the email in question referred to a Lantus patient experiencing recurrent hypoglycaemia. The Panel noted that it was of the utmost importance that such information about side-effects was processed by the company in accordance with, *inter alia*, the Code. However, the Panel noted that it was not for the Panel to infer detailed reasons to support the allegation. It was for the complainant to establish his/her case on the balance of probabilities. The Panel considered that the very general nature of the allegation was such that the subject matter of the allegation was unclear and the complainant had not discharged his/her burden of proof and thus ruled no breach of the Code including Clause 2.

With regard to the allegation that the email documented discussions around off-licence twice daily use of Lantus, the Panel noted that the email highlighted the field activities of named representatives in a given territory and was provided to representatives from another territory as an example of the types of Toujeo discussions being had with health professionals. The Panel noted Sanofi's submission that the intent was to share personal highlights to support teamwork and motivation and it was not intended to be directional. The Panel noted Sanofi's submission that the manager in question was currently managing the representatives from both territories. The Panel noted the manager's comment in the email provided to the second territory which stated 'It is abundantly clear that they [the first territory] are all having detailed conversations with HCPs and that this is translating to new patients for Toujeo'. In the Panel's view, the manager's email encouraged the second territory to learn from and adopt the activities of the first territory in terms of engagement with health professionals for the promotion of Toujeo. The Panel considered that the information therefore constituted briefing material.

The email in question mentioned conversations that three representatives had had with health professionals regarding patients on twice-daily Lantus who subsequently switched to Toujeo. The Panel noted Sanofi's submission that the references to twice-daily Lantus was not in any way directional in terms of how the product should be promoted. The Panel noted that the Code stated that 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 further noted that slides from the Operational Plan and Segmentation Workshop held in 2018 referred to a segment of customers described as 'Comfortable with patients having to take BD [twice-daily] Lantus as part of their basal bolus regime' and that such customers needed to 'See benefit of switching to Toujeo from Lantus in T1D [type 1 diabetes] and T2D [type 2 diabetes]'.

In the Panel's view the references to twice-daily use of Lantus in the email in question, without any qualification that such use was off-label and should not be proactively discussed, could encourage representatives, within the context of promoting Toujeo, to initiate discussions about twice-daily Lantus use, which was not within Lantus' licence, and a breach of the Code was ruled in relation to this representatives briefing materials. The Panel considered that the complainant had not provided evidence to demonstrate that on the balance of probabilities representatives went on to promote Lantus to health professionals in such a manner that was inconsistent with its SPC and ruled no breach of the Code.

With regard to the complainant's allegation that the patient support programme, Toujeo Coach, was being 'used and tracked by the representative', the Panel noted Sanofi's submission that Toujeo Coach was a Sanofi patient support programme that offered diabetes nurse specialist, psychologist and dietician coaching as well as support and access to educational resource and advice. According to Sanofi, it would be offered to a health professional or healthcare organisation once they had made the decision to prescribe Toujeo. The Panel noted that it was not clear why the complainant considered that reference to the Toujeo Coach service, in particular, that it was being used and tracked by a representative, was in breach of the Code. The Panel noted Sanofi's submission that the sales team was briefed on how to share the Toujeo Coach service as part of the Toujeo sales aid and accompanying briefing. The Panel noted Sanofi's submission that the representatives received reports of the number of patients enrolled on the Toujeo Coach programme at a clinical commissioning group (CCG) level. The complainant bore the burden of proof and had provided no evidence that in using and tracking the Toujeo Coach programme the representative had not complied with the relevant requirements of the Code. No breach was ruled.

The Panel was concerned that Sanofi did not consider the email in question to be briefing material. In the Panel's view, the email was clearly giving guidance regarding how the manager would like the representatives to conduct promotional activity for Toujeo and encouraging them to adopt such practices. The Panel considered that the failure to recognise that the email in question was briefing material and required certification raised concerns about the company's governance of such matters and meant that Sanofi had not maintained high standards. A breach was ruled accordingly.

The Panel noted that a breach of Clause 2 was a sign of particular censure and should be reserved for such use. The Panel did not consider that in the particular circumstances of this case Sanofi had brought discredit upon or reduced confidence in the pharmaceutical industry and ruled no breach of Clause 2.

An anonymous, non-contactable complainant who described themselves as a Sanofi employee complained about a manager's briefing with regard to the promotion of Lantus (insulin glargine 100 units/mL) and Toujeo (insulin glargine 300 units/mL). Both medicines were used in diabetes mellitus.

COMPLAINT

The complainant provided a copy of an email sent from a manager to his/her team of representatives in March 2018. The email chain including a regional head who endorsed the email. The complainant alleged that Sanofi acknowledged the manager's success but turned a blind eye as to how it was achieved, as his/her Toujeo market share was significantly higher since the initial promotion of Toujeo compared with other colleagues.

The complainant alleged that the manager actively encouraged representatives to have detailed discussions around patients with health professionals thereby resulting in audits and identification of patient groups. This was documented as best practice and included:

1 Patients to be identified and started on Toujeo via other ways and means of the agreed set policy in place (Rationale for Initiation, Continuation and Discontinuation (RICaD)).

2 Several mentions of adverse reactions with Lantus.

3 Discussions around off-licence, twice daily Lantus.

4 The Toujeo coach service for patients was being used and tracked by the representative.

When writing to Sanofi, the Authority asked it to bear in mind the requirements of Clauses 2, 3.2, 9.1, 15.2 and 15.9 of the Code.

RESPONSE

Sanofi submitted that it took its obligation under the Code very seriously and was concerned to receive such a complaint which appeared to originate from a member of staff. Sanofi submitted that it had conducted a comprehensive internal investigation, which included interviewing relevant staff. A review with the human resources department was also performed. Sanofi believed that there were three elements to this case: (1) the cultural aspects within Sanofi regarding compliance reporting and investigating (2) the intent behind the email and (3) the perception of inappropriate information contained within the email.

Culture

Sanofi stated that it had a very open culture with a robust process in place that encouraged reporting and dialogue around any compliance concerns, wherever these occurred within the business. This provided a number of opportunities for anyone to raise concerns about compliance, either with their own manager or senior leader(s), any other senior leader in the organisation or with the compliance team directly. Sanofi treated all concerns seriously and confidentially, and took appropriate action, regardless of the status of the person(s) involved or commercial/company objectives.

With respect to the complainant's concerns about named employees, the investigation had not identified any concerns over their conduct, management skills or compliance with the Code.

Intent behind the email

Sanofi provided details of the named manager's role and territory and explained that he/she also managed a second territory. The email in question was sent to the team in the second territory on their request and summarised highlights of the first territory team's week.

The email was an initiative from the manager used to share the team's work to support teamwork and motivation. It was not intended to be directional or giving actions for the team to complete and so Sanofi did not believe this was a briefing that required certification; it confirmed that the email was not certified.

Information in the email

Sanofi stated that the information in the email was simply a summary of highlights of the week and examples of operationalising of the sales model of the diabetes team. It shared examples of discussions team members had had with health professionals once patients suitable for treatment with the products they promoted had been identified.

The sales force promotional materials were provided including the Toujeo and Lantus sales aids and accompanying briefings. In addition, the Toujeo sales aid included relevant information on 'Toujeo Coach'. The 2018 Diabetes Operational plan, which was provided, was presented to the field teams in January 2018 to provide structure on how it was to promote Toujeo and Lantus.

Sanofi stated that Lantus was not approved for use twice daily and was therefore not discussed proactively by representatives. However, Sanofi recognised that some health professionals made the decision to use Lantus twice daily and so this verbatim information from the health professionals was recorded in the email. This was not encouragement of twice daily use of Lantus. Representatives did not proactively raise the use of Lantus twice daily in their calls with health professionals but explored with them patients with unmet medical need who might benefit from treatment with Toujeo. If a health professional referred to twice daily Lantus use, the representative would understand that this indicated a patient who might require a high dose of Lantus or had difficulty with recurrent hypoglycaemia, both of which represented unmet medical need that might be addressed by Toujeo. A promotional discussion of the benefits of Toujeo could then be based on the value of the product in addressing those needs.

Sanofi explained that Toujeo Coach was a Sanofi patient support program that offered diabetes nurse specialist, psychologist and dietician coaching as well as support and access to educational resources and advice. It could be offered to a health professional or healthcare organisation once they had decided to prescribe Toujeo. The sales team was briefed on how to share this offering as part of the Toujeo sales aid and accompanying briefing.

Sanofi explained that the agreed policy referred to was an NHS protocol that was external to Sanofi, which outlined the conditions that allowed initiation, continuation and discontinuation of the specific medicine to which it referred; it was provided by consultants to GPs with information to support their decision making. A copy was provided.

Sanofi submitted that it supported audits of diabetes care in the form of a programme provided as a medical and educational goods and services (MEGS) termed 'SDARs' – Sanofi Diabetes Analysis and Reporting Service. SDARs was a practice-based programme, delivered by a third-party provider, which identified sub-optimally controlled patients for review by practice staff. It was only introduced in brief by the sales team; if a health professional or healthcare organisation wanted more information on the service and subsequently used it, this was managed by Sanofi's NHS Outcome Managers (NOM) team in a non-promotional capacity and did not involve the sales teams (the representatives' briefing, the NOM briefing and the leavepiece for health professionals from NOM visit were provided). Sanofi noted that although some healthcare organisations in the region had had this MEGS support, none of the healthcare organisations referenced in the email in the complaint had received the service. The audits referred to in the complainant's email were all performed by the healthcare organisation directly and without Sanofi's involvement or support.

In conclusion Sanofi stated that based on its investigation it did not consider that the manager's or the senior manager's conduct had been inappropriate. Sanofi had found no evidence that any of its medicines had been promoted in a manner inconsistent with their marketing authorisations and it did not consider that any of the material provided or included in the email advocated any course of action which would breach the Code. Sanofi thus denied breaches of Clauses 2, 3.2, 9.1, 15.2 and 15.9.

Following a request for further information, Sanofi submitted that its pharmacovigilance department had no record of any adverse reaction reports or off label use reports that matched any of the detail in the email in question. Sanofi provided copies of training material for employees on reporting adverse reactions and events of special interest. Sanofi stated that personnel were trained during their onboarding and refresher training was conducted annually.

Sanofi submitted that a comment in the email by one of the representatives which stated 'track using enrolment data' referred to the representative checking whether there was an increase in the number of patients enrolled on to the Toujeo Coach programme in the locality. Sanofi explained that representatives received reports of the number of patients enrolled on to the Toujeo Coach programme at a clinical commissioning group (CCG) level.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable and therefore could not be contacted for further information. The Constitution and Procedure 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.

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. Briefing material must comply with the relevant requirements of the Code and was subject to the certification requirements of Clause 14. 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 the complainant's allegation that the manager was encouraging identification of patients for Toujeo outside of the agreed policy. The Panel noted Sanofi's submission that the agreed policy was an NHS protocol that was external to Sanofi and was provided by consultants to general practitioners. The Panel noted that two representatives made reference to the agreed policy being a barrier in certain circumstances. The Panel noted that Clause 3.2 of the Code required a medicine to be promoted in a manner that was not inconsistent with the particulars in its summary of product characteristics (SPC). The Code did not state that a medicine must be promoted within the terms of local, regional or national guidelines. However, the Code required information, claims and comparisons to be, *inter alia*, accurate, balanced, fair, based on an up-to-date evaluation of the evidence and not misleading either directly or by implication. The Panel did not consider that the complainant had provided any evidence which demonstrated that any of Sanofi's representatives had promoted Toujeo outside the terms of its marketing authorisation or that the email in question advocated such use and therefore no breach of Clauses 3.2, 15.2 and 15.9 were ruled on that point.

The Panel noted the complainant's statement that 'Several mentions of adverse reactions with Lantus' were documented in the email. It was not entirely clear from the complaint what he/she was alleging to be in breach of the Code in relation to adverse events. The complainant appeared to have made a general allegation but had not submitted any detailed reasons. The complainant was anonymous and could not be contacted for more information. The Panel noted that the email in question did refer to a Lantus patient experiencing recurrent hypoglycaemia. The Panel noted that it was of the utmost importance that such information about side-effects was processed by the company in accordance with, *inter alia*, the Code. However, the Panel noted that it was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. It was for the complainant to establish his/her case on the balance of probabilities. The Panel considered that the very general nature of the allegation was such that the complainant had not discharged his/her burden of proof and the subject matter of the allegation was unclear. The Panel on this narrow ground ruled no breach of Clauses 15.2, 15.9 and 9.1. The Panel consequently ruled no breach of Clause 2.

The Panel noted the complainant's allegation that the email documented discussions around off-licence twice daily use of Lantus. The Panel noted that the email highlighted the field activities of five named representatives in a given territory and was provided to representatives from another territory as an example of the types of Toujeo discussions that the first territory was having with health professionals. The Panel noted Sanofi's submission that the intent was to share personal highlights to support teamwork and motivation and it was not intended to be directional. The Panel noted Sanofi's submission that the manager in question was currently managing the representatives from both territories. The Panel noted the manager's comment in the email provided to the second territory which stated 'It is abundantly clear that they … are all having detailed conversations with HCPs and that this is translating to new patients for Toujeo'. In the Panel's view, the manager's email encouraged the second territory to learn from and adopt the activities of the first territory in terms of engagement with health professionals for the promotion of Toujeo. The Panel considered that the information therefore constituted briefing material.

The email in question mentioned conversations that three representatives had had with health professionals regarding patients on twice-daily Lantus who subsequently switched to Toujeo. The Panel noted Sanofi's submission that the references to twice-daily Lantus was not in any way directional in terms of how the product should be promoted. The Panel noted that Clause 15.9 stated that 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 further noted that slides from the Operational Plan and Segmentation Workshop held in 2018 referred to a segment of customers described as 'Comfortable with patients having to take BD [twice-daily] Lantus as part of their basal bolus regime' and that such customers needed to 'See benefit of switching to Toujeo from Lantus in T1D [type 1 diabetes] and T2D [type 2 diabetes]'.

In the Panel's view the references to twice-daily use of Lantus in the email in question, without any qualification that such use was off-label and should not be proactively discussed, could encourage representatives, within the context of promoting Toujeo, to initiate discussions about twice-daily Lantus use, which was not within Lantus' licence, and a breach of Clause 15.9 was ruled. The Panel considered that the complainant had not provided evidence to demonstrate that on the balance of probabilities representatives went on to promote

Lantus to health professionals in such a manner that was inconsistent with its SPC and ruled no breach of Clauses 3.2 and 15.2.

The Panel noted the complainant's allegation that the patient support programme, Toujeo Coach, was being 'used and tracked by the representative'. The Panel noted Sanofi's submission that Toujeo Coach was a Sanofi patient support programme that offered diabetes nurse specialist, psychologist and dietician coaching as well as support and access to educational resource and advice. According to Sanofi, it would be offered to a health professional or healthcare organisation once they had made the decision to prescribe Toujeo. The Panel noted that as above it was not clear why the complainant considered that reference to the Toujeo Coach service, in particular that it was being used and tracked by a representative, was in breach of the Code. The Panel noted Sanofi's submission that the sales team were briefed on how to share the Toujeo Coach service as part of the Toujeo sales aid and accompanying briefing. The Panel noted Sanofi's submission that the representatives received reports of the number of patients enrolled on the Toujeo Coach programme at a CCG level. The complainant bore the burden of proof and had provided no evidence that in using and tracking the Toujeo Coach programme the representative had not complied with the relevant requirements of the Code. No breach of Clause 15.2 was ruled.

The Panel noted Sanofi's submission that the email was not intended to be directional or to give actions for the team to complete and therefore Sanofi did not consider it to be briefing material that required certification. The Panel noted its comments and rulings above on this point. The Panel was concerned that Sanofi did not consider the email in question to be briefing material. The email was provided by a manager to a group of representatives to demonstrate how the activities of another group of representatives had translated into 'new patients for Toujeo'. In the Panel's view, the email was clearly giving guidance regarding how the manager would like the representatives to conduct promotional activity for Toujeo and encouraging them to adopt such practices. The Panel considered that the failure to recognise that the email in question was briefing material and required certification raised concerns about the company's governance of such matters and meant that Sanofi had not maintained high standards. A breach of Clause 9.1 was ruled accordingly.

The Panel noted that a breach of Clause 2 was a sign of particular censure and should be reserved for such use. The Panel did not consider that in the particular circumstances of this case Sanofi had brought discredit upon or reduced confidence in the pharmaceutical industry and ruled no breach of Clause 2.

During the consideration of this Case, the Panel noted that the email in question referred to an adverse reaction in one patient and off-label use of Lantus in specific patients. The Panel noted Sanofi's submission that its pharmacovigilance department had no record of relevant reports. Both Sanofi's onboarding and annual pharmacovigilance training materials stated that employees must report such matters. The Panel was extremely concerned to note that the adverse event and reports of off-label use with Lantus had not been reported to its pharmacovigilance department. Given the email's circulation the Panel was extremely concerned that no-one had reported the events. The Panel asked that Sanofi be made aware of its concerns in this regard and considered it would be helpful if Sanofi reviewed its activities in this area to ensure that all such matters were reported in accordance with company procedures, the Code and relevant legislation.

Complaint received **16 March 2018**

Case completed **19 December 2018**