CASE AUTH/3481/3/21

ANONYMOUS SANOFI EMPLOYEE v SANOFI

Promotion of Suliqua

An anonymous, non-contactable complainant, who described him/herself as a Sanofi employee, complained about the content of recent internal communications in relation to the promotion of Suliqua (insulin glargine with lixisenatide). Suliqua was indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors.

The complainant stated that he/she was concerned at the content of recent emails and the content of a WhatsApp group. An internal email had been circulated congratulating a manager on successfully gaining formulary guidance for Suliqua across a named region. The complainant alleged that the formulary positioning, however, contravened Suliqua's licence which stated 'Suliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors'. The complainant queried whether off-licence discussions had occurred with health professionals (or whether they were fully aware of the licence) based on this formulary position and how the information could have been shared internally (by senior leadership) potentially endorsing off-licence discussions. The complainant further queried why no-one else had realised this issue and questioned if everyone was aware of the Suliqua licence.

In addition, the complainant stated that a WhatsApp group entitled 'Suliqua info' used a group image a signed prescription of Suliqua and the complainant alleged that the use of this image was ethically questionable.

The detailed response from Sanofi is given below.

The Panel noted that the complainant referred to an email which had been circulated by a Sanofi employee to notify his/her team of the adoption of Suliqua onto a local area prescribing committee (APC) formulary and was subsequently circulated by senior sales employees to other internal staff.

The original email included a screenshot of the APC website which displayed the formulary status for Suliqua; the Panel noted Sanofi's submission that the licensed indication did not correlate with the inappropriately worded Suliqua listing which was determined independently by the local APC formulary.

The Panel noted Sanofi's submission that the email in question was not intended to be a sales force briefing; the intent of sharing it was to congratulate the account team on the APC's adoption of Suliqua.

In the Panel's view, the email encouraged the other teams to learn from, and adopt, the activities of the first team in terms of engagement with health professionals for the promotion of Suliqua. The Panel considered that the information therefore constituted briefing material.

In the Panel's view, the reproduction of the formulary text for Suliqua and positive comments about its adoption in the email in question, without any qualification that such use was off-label and should not be proactively discussed, could have, on the balance of probabilities, directly or indirectly, encouraged representatives to promote Suliqua in a manner that was inconsistent with its licence, and a breach of the Code was ruled. High standards had not been maintained and a breach of the Code was ruled.

The Panel noted that the complainant bore the burden of proof and considered that he/she had not provided evidence to demonstrate that, on the balance of probabilities, representatives had promoted Suliqua to health professionals in such a manner that was inconsistent with its SPC and ruled no breach of the Code.

The Panel noted Sanofi's submission that all promotional staff members in circulation of the email had received full training on the Suliqua SPC and were aware of the licensed indications. The Panel was concerned that staff had apparently not recognised that the formulary listing, as reproduced in the email in question, was inconsistent with the SPC. The Panel noted that the matter raised by the complainant appeared to fall within the training requirements in the Code. Noting Sanofi's submissions about training on the SPC and the Panel's concerns as noted above, the Panel did not consider that the complainant had established, on the balance of probabilities, that staff were not aware of the Suliqua licence, as alleged, and no breach of the Code was ruled in that regard.

The Panel further noted that the complainant referred to a WhatsApp group, entitled 'Suliqua info', and had provided an image of the group photograph which showed part of a signed Suliqua prescription; the complainant alleged that the use of this image was ethically questionable.

The Panel noted that the image used for the WhatsApp group, entitled 'Suliqua info', displayed part of a prescription form, and a health professional signature which was not legible; the image did not have any identifiable data for the patient nor, due to illegibility, the health professional. The image showed the endorsement section where details of the medicine prescribed were given. The Panel considered that the complainant had not explained why, in his/her view, the image was 'ethically questionable' and therefore ruled no breach of the Code in that regard.

The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and should be reserved for such use and accordingly ruled no breach.

An anonymous, non-contactable complainant, who described him/herself as a Sanofi employee, complained about the content of recent internal communications in relation to the promotion of Suliqua (insulin glargine with lixisenatide).

Suliqua was indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors.

COMPLAINT

The complainant stated that he/she was concerned at the content of recent emails, as well as the content of a WhatsApp group. An internal email had been circulated congratulating a manager on successfully gaining formulary guidance for a Sanofi product (Suliqua) across a named region. The complainant alleged that the formulary positioning, however, contravened Suliqua's licence which stated 'Suliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors'. The complainant stated that he/she had raised the issue internally. The complainant queried whether off-licence discussions had occurred with health professionals (or whether they were fully aware of the licence) based on this formulary position and how the information could have been shared internally (by senior leadership) potentially endorsing off-licence discussions. The complainant further queried why no-one else had realised this issue and questioned if everyone was aware of the Suliqua licence.

In addition, the complainant stated that a senior leader recently showed him/her a WhatsApp group entitled 'Suliqua info', which was used as a communication tool. The group image was a real-life signed prescription of Suliqua and the complainant alleged that the use of this image was ethically questionable. The complainant attached evidence of the emails and WhatsApp image of the signed prescription (copy provided) and believed these were serious breaches of the Code.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 3.2, 9.1, 15.9 and 2 of the Code.

RESPONSE

Sanofi stated that it took its obligation under the Code very seriously and was concerned to have received such a complaint originating from a member of staff. Noting the lack of evidence provided by the complainant to substantiate his/her complaint, Sanofi conducted an internal investigation, which had included interviews with members of staff while taking particular care to protect the anonymity of the complainant. Sanofi stated that it did not believe that this had adversely affected its response and it was attempting to respond in full, given the limited information included in the original complaint.

Sanofi stated that whilst it was addressing this specific complaint, it had noted the similarities with the subsequent complaints from complainants who described themselves as health professionals, Case AUTH/3486/3/21 and Case AUTH/3491/3/21.

Positioning of Suliqua within a local APC Formulary

Sanofi submitted that the current licensed indications for Suliqua, as stated in the summary of product characteristics (SPC) for Suliqua 100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen, last revised 10 August 2020, were:

> 'Suliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors.'

Prior to 9 March 2020, the Suliqua licensed indications in the SPC last revision date 13 September 2018 were:

> 'Suliqua is indicated in combination with metformin for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin.'

The wording within the APC Formulary for Suliqua at the time of this complaint and as in the screenshot sent by the complainant on the named area's APC website (noting this was formulated and decided upon independently of Sanofi) stated:

> 'Type 2 diabetes mellitus in combination with oral antidiabetic drugs (eg metformin, pioglitazone, or a sulfonylurea) or basal insulin, or both, when adequate glycaemic control has not been achieved with these drugs.'

Sanofi submitted that, although the SPC for Suliqua was updated in March 2020, neither the original nor updated licensed indication correlated with the inappropriately worded Suliqua listing which was determined by the local APC Formulary.

Sanofi responded to the issues/questions raised by the complainant.

1 'Have off-license discussions occurred with HCPs (or are they fully aware of the license) based on this formulary position?'

Sanofi noted this was a question from the complainant rather than a specific complaint, and no evidence had been provided by the complainant to support his/her complaint/question. Further to Sanofi's internal investigation, there was no evidence within the Sanofi customer relationship management (CRM) system, nor from interviews with relevant staff members who had had interactions with external stakeholders in this locality, that promotion outside of the Suliqua licence had taken place.

Sanofi stated that it was not privy to the discussions that took place within the APC formulary committee itself, which Sanofi believed was in November 2020, and were unaware of the product's subsequent acceptance onto formulary until it was placed in the public domain and seen on the APC website by the representative in February 2021.

Sanofi acknowledged that the stated position formulated and approved by the APC formulary committee was not aligned with the licensed indication for Suliqua. However, this formulary listing was set independently of Sanofi and there had not been any evidence submitted by the complainant nor discovered during its internal investigation that Sanofi had influenced or otherwise provided this wording. Sanofi refuted a breach of Clause 3.2 and the allegation that it might not have maintained high standards (Clause 9.1).

2 'How could this be shared internally (by senior leadership), potentially endorsing off-license discussions?'

An email was shared internally congratulating the account team on the APC's adoption of Suliqua. The intent behind the email was to recognise this local success, in the context of the challenges seen within the external environment associated with Covid-19 over the last year.

The interviewees questioned about the email responded that they had not examined the specific details of the product's listing as the purpose of the communication was simply and singly to recognise the local teamwork and at a challenging time for all concerned. It was not, and was not intended to be, a salesforce briefing, and no evidence had been provided by the complainant or uncovered in Sanofi's investigation to the contrary. Sanofi refuted breaches of Clauses 15.9 or 9.1.

3 'How has no-one else realised this issue and is everyone aware of the Suliqua license?'

As stated above, Sanofi acknowledged that the email was forwarded to other internal staff without reference to, or comment on, Suliqua's specific positioning in the formulary. This aspect was not referred to in the original email, nor in subsequent emails, which were simply acknowledging the efforts of the team. All promotional staff members in circulation of this email had received full training on the Suliqua SPC and were aware of the licensed indications. The staff members interviewed had confirmed that they had not been aware of, nor recognised the detail of, the listing of Suliqua on the APC formulary until this was specifically brought to their attention during the investigation of this complaint. Sanofi noted there had not been evidence submitted or uncovered to the contrary. Sanofi refuted a breach of Clause 9.1 with respect to this.

WhatsApp Group – alleged use of image of a real-life signed prescription of Suliqua

Sanofi spoke with the administrator of the WhatsApp group in question and noted that the group, titled 'Suliqua Info', was set up around the time of the product's launch (May 2019) to facilitate communication amongst the internal launch team. This WhatsApp group had not been active for some time, it had been archived and the administrator had advised that the content was no longer available within the application. All members of this group were internal; the members' job roles were provided by the group's administrator and predominantly consisted of commercial employees. There was no evidence that any content on this group had been non-compliant.

The prescription image provided by the complainant was a copy of a prescription which had been provided to Sanofi by an external health professional post-launch. The purpose of sharing this was to show how a Suliqua prescription would appear when produced by an electronic prescribing system. Before provision to Sanofi, care was taken to ensure there was no identifiable data on the prescription, either of a patient or a health professional. Sanofi refuted that this image was, in anyway, 'ethically questionable' as described by the complainant, noting this assertion was not substantiated by the complainant.

In relation to the use of the WhatsApp group and the image used, Sanofi had not identified any evidence suggesting that high standards had not been maintained and refuted a breach of Clause 9.1.

Overall Conclusion

Sanofi was confident that its sales teams had been appropriately trained on the Suliqua licence and had conducted themselves accordingly. There was no evidence that, in the course of their interactions, Sanofi had promoted the product in an off-label manner, nor that it would result in the APC listing of Suliqua in a way that was inconsistent with the licence. The purpose of the highlighted email was to congratulate the local team that the product had been placed on the formulary as an option for health professionals to use, but the specifics of the positioning were not recognised, commented on nor endorsed. Sanofi refuted breaches of Clauses 3.2, 9.1, 15.9 and 2.

Similarly, Sanofi had no evidence that the internal WhatsApp Group raised by the complainant was used inappropriately. Sanofi refuted any breach of Clauses 3.2, 9.1, 15.9 or 2.

Sanofi stated that it was disappointed that the complainant had not fully escalated their concerns internally, as this would have enabled earlier attention to this matter. Sanofi were therefore taking the opportunity to re-communicate to its staff the availability of a confidential hotline, in addition to other reporting avenues, to raise concerns internally should it be needed.

As Sanofi's attention had been drawn to the APC formulary position, Sanofi had proactively contacted the APC through its medical department to advise them of the inconsistency between the SPC indications and the formulary wording, noting that this was wholly independent of Sanofi. Sanofi stated that it had received confirmation from the APC on 17 March 2021 advising Sanofi that they had amended their Suliqua entry.

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. All complaints were judged on the evidence provided by the parties.

The Panel noted that Sanofi had referred to similar recent complaints and considered that each complaint would be considered separately on the evidence submitted in each case.

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. 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 noted that the complainant referred to, and provided, an email which had been circulated by a Sanofi employee to notify his/her team of the adoption of Suliqua onto a local Area Prescribing Committee (APC) formulary and was subsequently circulated by senior sales employees to other internal staff.

The original email included a screenshot of the APC website which displayed the formulary status for Suliqua as Specialist Initiation (SI) for 'Type 2 diabetes mellitus in combination with oral antidiabetic drugs (e.g. metformin, pioglitazone, or a sulfonylurea) or basal insulin, or both, when adequate glycaemic control has not been achieved with these drugs'.

The Panel noted Sanofi's submission that although the SPC for Suliqua was updated in March 2020, neither the original nor updated licensed indication correlated with the inappropriately worded Suliqua listing which was determined independently by the local APC formulary.

The Panel noted that according to its SPC, current at the time of the complaint, Suliqua was 'indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors'.

The Panel noted Sanofi's submission that the email in question was not intended to be a sales force briefing; the intent of sharing it was to congratulate the local account team on the APC's adoption of Suliqua. The Panel further noted Sanofi's submission that the recipients had not examined the specific details of the formulary listing.

In the Panel's view, the email which was shared by senior managers to congratulate account teams on the APC's adoption of Suliqua, encouraged the remaining teams to learn from, and adopt, the activities of the first team in terms of engagement with health professionals for the promotion of Suliqua. The Panel considered that the information therefore constituted briefing material.

The Panel noted that Clause 15.9 further 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. In the Panel's view, the reproduction of the formulary text for Suliqua and positive comments about its adoption in the email in question, without any qualification that such use was off-label and should not be proactively discussed, could have, on the balance of probabilities, directly or indirectly, encouraged representatives to promote Suliqua in a manner that was inconsistent with its licence, and a breach of Clause 15.9 was ruled. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted Sanofi's submission that it found no evidence in its customer relationship management (CRM) system, nor through interviews with relevant staff members, that promotion outside of the Suliqua licence had taken place. The Panel noted that the complainant bore the burden of proof and considered that he/she had not provided evidence to demonstrate that, on the balance of probabilities, representatives had promoted Suliqua to health professionals in such a manner that was inconsistent with its SPC and ruled no breach of Clause 3.2.

The Panel noted Sanofi's submission that all promotional staff members in circulation of the email had received full training on the Suliqua SPC and were aware of the licensed indications; the staff members interviewed had confirmed that they had not been aware of, nor recognised the detail of, the listing of Suliqua on the APC formulary until this was specifically brought to their attention during the investigation of this complaint and there had not been evidence submitted or uncovered to the contrary. The Panel was concerned that promotional staff who had received full training on the SPC had apparently not recognised that the formulary listing, as reproduced in the email in question, was inconsistent with the SPC. The Panel noted that the matter raised by the complainant appeared to fall within the training requirements in the Code. The Panel noted that the company had not been asked to respond in relation to Clauses 15.1 or 16.1 of the Code and thus the Panel dealt with the matter under Clause 9.1. Noting Sanofi's submissions about training on the SPC and the Panel's concerns as noted above, the Panel did not consider that the complainant had established, on the balance of probabilities, that staff

were not aware of the Suliqua licence, as alleged, and no breach of Clause 9.1 was ruled in that regard.

The Panel further noted that the complainant referred to a WhatsApp group, entitled 'Suliqua info', and had provided an image of the group photograph which showed part of a signed Suliqua prescription; the complainant alleged that the use of this image was ethically questionable. The Panel noted Sanofi's submission that the WhatsApp group was set up around the time of the product's launch (May 2019) to facilitate communication amongst the internal launch team and members of the group included various managers including senior sales managers. The Panel further noted Sanofi's submission that the image provided by the complainant was a copy of a prescription which had been provided to Sanofi by an external health professional and was shared to show how a Suliqua prescription would appear when produced by an electronic prescribing system.

The Panel noted that the image, which was for internal use, displayed part of a prescription form, and a health professional signature which was not legible; the image did not have any identifiable data for the patient nor, due to illegibility, the health professional. The image showed the endorsement section where details of the medicine prescribed were given. The Panel considered that the complainant had not explained why, in his/her view, the image was 'ethically questionable' and therefore ruled no breach of Clause 9.1 in that regard.

The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and should be reserved for such use and accordingly ruled no breach.

Complaint received **2 March 2021**

Case completed **10 November 2021**