CASE AUTH/3491/3/21 ***NO BREACH OF THE CODE***

COMPLAINANT v SANOFI

Alleged off-licence promotion of Suliqua

An anonymous, non-contactable complainant who described him/herself as a health professional complained about the promotion of Suliqua (pre-filled pen of insulin glargine and lixisenatide) by Sanofi.

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 as a pharmaceutical advisor in a named region, he/she was contacted by a diabetes nurse, who wished to start a patient on Suliqua and, according to the information the nurse received from the company, considered that he/she could do that in addition to leaving the patient on basal insulin. The complainant stated that the nurse had contacted him/her for advice and following a BNF search, it was clear that that was incorrect and could have potentially led to an insulin overdose. The complainant queried the conduct of Sanofi and direction provided, if this was what it was asking its employees to do. The complainant considered that this was a serious issue and one that could have led to a serious event if he/she had not intervened.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that whilst the complainant had not presented any evidence to substantiate his/her complaint, the listing of Suliqua on the local APC formulary, which according to Sanofi was developed independently of Sanofi and was inconsistent with the summary of product characteristics (SPC) for Suliqua, appeared to be similar to the proposed approach discussed between the diabetes nurse and the pharmaceutical advisor.

The Panel noted Sanofi's submission that it had not identified any evidence from its investigations, nor had any evidence been presented, that Sanofi had provided information leading to the inappropriate APC Formulary positioning of Suliqua.

The Panel noted that the APC formulary stated that Suliqua was indicated 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' whilst the SPC for Suliqua stated that it 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 that Sanofi acknowledged that whilst the APC formulary position was not aligned with Suliqua's licence, this was set independently of Sanofi and it had not been demonstrated, on the balance of probabilities, that Sanofi influenced this position.

The Panel noted Sanofi's submission that without any identifiable details of the diabetes nurse, they could not examine the record of the Sanofi interaction. The Panel noted that Sanofi had only reviewed a sample of call records but noted its submission that from its broader investigations, it had found no evidence in its customer relationship management (CRM) system, nor from interviews with relevant staff members, that promotion outside of the Suliqua licence had taken place. The Panel did not have a copy of the information in question. Sanofi made no submission with regard to materials used in the named area. The Panel noted that whilst according to Sanofi the SPC was updated with the current indication in mid-March 2020, it appeared that the training on the updated SPC was only certified on 20 April 2020. Nonetheless, the Panel did not consider that the complainant had discharged his/her burden of proof that a Sanofi representative had engaged in off-licence discussions about Suliqua with health professionals and thus, on the evidence before it, ruled no breaches of the Code.

The Panel further noted Sanofi's submission that its sales representatives had been trained and validated on the Suliqua SPC and all promotional materials had been reviewed and certified before use; a copy of Sanofi's SOP requirements for briefing and training customer-facing teams was also provided. The Panel, therefore, did not consider, on the evidence before it, that Sanofi had advocated any course of action which would be likely to lead to a breach of the Code and no breach was ruled.

The Panel noted its comments and rulings of no breach above and consequently ruled no breaches of the Code, including no breach of Clause 2.

An anonymous complainant, who could not be contacted on the details provided, described him/herself as a health professional complained about the promotion of Suliqua (pre-filled pen of insulin glargine and lixisenatide) by Sanofi.

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 as a pharmaceutical advisor in a named region, he/she was concerned after being contacted by a diabetes nurse, who wished to start a patient on Suliqua and, according to the information the nurse received from the company, considered that he/she could do that in addition to leaving the patient on basal insulin. The complainant stated that the nurse had contacted him/her for advice and following a BNF search, it was clear that that was incorrect and could have potentially led to an insulin overdose. The complainant queried the conduct of Sanofi and direction provided, if this was what it was asking its employees to do. The complainant considered that this was a serious issue and one that could have led to a serious event if he/she had not intervened. The complainant stated that he/she would also raise the matter with senior consultants within the Clinical Commissioning Group.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 3.2, 7.2, 9.1, 15.9 and 2 of the Code.

RESPONSE

Sanofi stated that it was very concerned to receive such a complaint related to alleged communication from Sanofi about a company product and had noted the similarities with two other complaints (Cases AUTH/3481/3/21 and AUTH/3486/3/21). In view of the lack of evidence provided by the complainant to substantiate his/her complaint, Sanofi had used information gathered from the investigation of Cases AUTH/3481/3/21 and AUTH/3486/3/21 as part of the investigation into this complaint. These investigations included interviewing staff who covered that locality and a review of a sample of call records for the complainant's area.

Sanofi noted that the complainant had not presented any evidence to substantiate his/her complaint, and that his/her complaint did not refer to information that he/she had received from Sanofi but referred to information which they believed a third party (diabetes nurse) might have received. This was also not supported by any evidence from the complainant. However, as covered in detail in the responses to Cases AUTH/3481/3/21 and AUTH/3486/3/21, the listing of Suliqua on the local APC formulary, developed independently of Sanofi and inconsistent with the summary of product characteristics (SPC) for Suliqua, appeared to be similar with the proposed approach discussed between the diabetes nurse and the pharmaceutical advisor.

Sanofi stated that in its response, it addressed the requirements of Clauses 3.2, 7.2, 9.1, 15.9 and 2 of the 2019 Code.

Suliqua listing within the named APC Formulary:

Whilst it was not raised by the complainant, Sanofi knew from its recent investigation of Cases AUTH/3481/3/21 and AUTH/3486/3/21 that the wording, up to the 17 March 2021, in the named Area Prescribing Committee (APC) Formulary for Suliqua included combination with basal insulin and advised the product was approved within this locality for specialist initiation only:

> '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 had not been achieved with these drugs.'

Sanofi stated that it had not identified any evidence from its investigations, nor had any evidence been presented, that Sanofi provided information leading to the inappropriate APC Formulary positioning of Suliqua. However, once Sanofi's attention had been drawn to the formulary wording, the company proactively contacted the APC through its medical department to advise it of the inconsistency between the SPC and the formulary listing, noting that the committee's decision was wholly independent of Sanofi. Sanofi noted that on 17 March 2021, the APC confirmed that it had amended the Suliqua entry (screenshot of the website was provided).

The current licensed indication for Suliqua, as stated in the SPC, (copy provided) was:

> '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.'

Sanofi noted that before 9 March 2020, the Suliqua SPC read:

> ‘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.’

Although the SPC for Suliqua was updated in March 2020, neither the original nor the updated licensed indication included co-administration with basal insulin.

Sanofi noted that the complainant stated that the diabetes nurse who contacted him/her had considered that they could start Suliqua in addition to leaving a patient on basal insulin, based on information they had received from the company. Without any identifiable details of the diabetes nurse, Sanofi could not investigate as to whether it had a record of a Sanofi interaction with him/her. From Sanofi’s broader investigations, there was no evidence within its customer relationship management (CRM) system, nor from interviews with relevant staff who had had interactions with external stakeholders in this locality, that promotion outside of the Suliqua licence had taken place. Sanofi submitted that its representatives had been trained and validated on the Suliqua SPC (training validation documents enclosed) which aligned with the two SPCs provided and all Suliqua promotional materials had been reviewed and certified before use. Sanofi reiterated that without more information of the nature of the alleged interaction, it could not investigate in more depth. There was no evidence presented that Sanofi had not maintained high standards.

Sanofi refuted that it had breached the Code in its promotion of Suliqua and specifically in relation to Clauses 3.2, 7.2, 9.1, 15.9 and 2.

PANEL RULING

The Panel noted that according to the complainant, he/she was contacted by a nurse who, based on information provided by Sanofi, considered that a patient could be started on Suliqua whilst remaining on basal insulin which was not so and could have led to an insulin overdose.

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 Sanofi’s submission that whilst the complainant had not presented any evidence to substantiate his/her complaint, the listing of Suliqua on the local APC formulary which, according to Sanofi, was developed independently of Sanofi and was inconsistent with the SPC for Suliqua, appeared to be similar to the proposed approach discussed between the diabetes nurse and the pharmaceutical advisor.

The Panel noted Sanofi’s submission that it had not identified any evidence from its investigations, nor had any evidence been presented, that Sanofi had provided information leading to the inappropriate APC Formulary positioning of Suliqua.

The Panel noted that the APC formulary stated Suliqua was indicated 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’ whilst the SPC for Suliqua stated that it 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 that Sanofi acknowledged that whilst the APC formulary position was not aligned with Suliqua's licence, this was set independently of Sanofi and it had not been demonstrated, on the balance of probabilities, that Sanofi influenced this position.

The Panel noted Sanofi's submission that without any identifiable details of the diabetes nurse, they could not examine the record of the Sanofi interaction. The Panel noted that Sanofi had only reviewed a sample of call records but noted its submission that from its broader investigations, it had found no evidence in its customer relationship management (CRM) system, nor from interviews with relevant staff members, that promotion outside of the Suliqua licence had taken place. The Panel did not have a copy of the information in question. Sanofi made no submission with regard to materials used in the named area. The Panel noted that whilst, according to Sanofi, the SPC was updated with the current indication in mid-March 2020, it appeared that the training on the updated SPC was only certified on 20 April 2020. Nonetheless, the Panel did not consider that the complainant had discharged his/her burden of proof that a Sanofi representative had engaged in off-licence discussions about Suliqua with health professionals and thus, on the evidence before it, ruled no breach of Clauses 3.2 and 7.2 in that regard.

The Panel further noted Sanofi's submission that its sales representatives had been trained and validated on the Suliqua SPC and all promotional materials had been reviewed and certified before use; a copy of Sanofi's SOP requirements for briefing and training customer-facing teams was also provided. The Panel, therefore, did not consider, on the evidence before it, that Sanofi had advocated any course of action which would be likely to lead to a breach of the Code; no breach of Clause 15.9 was ruled.

The Panel noted its comments and rulings of no breach above and consequently ruled no breach of Clauses 9.1 and 2.

Complaint received **15 March 2021**

Case completed **6 October 2021**