CASE AUTH/3486/3/21 ***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 was perturbed to be notified of an out-of-licence formulary positioning of Suliqua which was not licensed to be used with basal insulin as could be found from its summary of product characteristics (SPC). The complainant was concerned that representatives might have/would have been having off-licence discussions/promotion, leading to this positioning. The complainant referred to a webpage of a local Area Prescribing Committee (APC) formulary for evidence.

The detailed response from Sanofi is given below.

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 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 by the local APC formulary. The Panel noted Sanofi's submission with regard to the interactions between it and the APC in relation to Suliqua. The Panel noted that Sanofi acknowledged that whilst the APC formulary position was not aligned with Suliqua's licence, it was set independently of Sanofi and there had been no evidence that Sanofi influenced this position.

The Panel noted Sanofi's submission that the complainant had provided no evidence that Sanofi provided any support to the local APC's application(s). 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 further noted Sanofi's submission that Sanofi's formulary pack and its associated briefing document were aligned with the Suliqua indication. The Panel considered that the complainant had

not demonstrated that Sanofi employees had engaged in off-licence discussions or promotion about Suliqua with health professionals leading to its off-licence listing as alleged and thus ruled no breaches of the Code.

The Panel did not consider that the complainant had raised an allegation in relation to briefing and therefore ruled no breach of the Code.

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 (insulin glargine with lixisenatide) 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 perturbed to be notified of an out of licence formulary positioning of Suliqua (link provided) which was not licensed to be used with basal insulin as could be found from its summary of product characteristics (SPC). The complainant was concerned that the representatives might have/would have been having off-licence discussions/promotion, leading to this positioning. The complainant stated that he/she would be interested to know Sanofi's position on this serious issue and how they would be rectifying it in the future. The complainant referred to a web link of a local APC formulary for evidence.

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

RESPONSE

Sanofi noted that the complainant raised a concern associated with his/her notification of the positioning of Suliqua within a named Area Prescribing Committee Formulary and provided a link to the formulary website.

Sanofi stated that it was very concerned to receive such a complaint related to a Sanofi product and had noted the similarities with two other complaints received via the PMCPA (Case AUTH/3481/3/21 and Case AUTH/3491/3/21). Per Sanofi's response to Case AUTH/3481/3/21, Sanofi noted the listing of the Sanofi medicine on the named local Area Prescribing Committee (APC) Formulary was made wholly independently of Sanofi. Sanofi stated that it had utilised information gathered from the investigation of Case AUTH/3481/3/21 in order to respond to this complaint, which included interviewing staff who covered this locality (noting the anonymous nature of the complaint, but reflecting the area related to the APC). Additionally, the investigation of this complaint involved reviewing available formulary materials for Suliqua promotion and a review of a sample of call records for the health professional's presumed area.

Sanofi noted that the complainant did not specify how he/she had been made aware, or by whom, of the formulary listing of Suliqua (which as already described, was made independently

of Sanofi). Sanofi also noted the complainant's concern that Sanofi representatives might have contributed to this positioning, but that no evidence had been provided to support this complaint.

Positioning of Suliqua within the named APC Formulary:

Sanofi stated that the current licensed indication for Suliqua as stated in the SPC for Suliqua 100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen, last revised 10 August 2020.

> '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 indication in the SPC last revision date of 13 September 2018 was:

> '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 (as downloaded by the PMCPA case preparation manager for this complaint) at the time of this complaint was:

> '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 APC Formulary.

Complaint Raised by the Complainant Relates to their Notification of the APC Formulary Positioning of Suliqua.

Sanofi submitted information about its role in the addition of Suliqua to the APC formulary. Suliqua discussions between Sanofi representatives and relevant local specialists in this area began in 2019. Sanofi had been unable to interview one of the key sales representatives involved, as they were no longer with the company. This representative was working in this locality until the end of January 2020. A Sanofi NHS account manager and area business manager met jointly with the APC Formulary Secretary in January 2020. There was no record of any materials being left with the customer at this time. The local sales representative separately recorded that they had promotional calls with some local diabetes specialists in the first quarter of 2020 and Sanofi understood that one of these specialists was preparing a formulary submission for Suliqua consideration in March 2020. Sanofi stated that it was unsure whether this submission progressed at this time or whether the process was impacted by pressures associated with Covid-19. As a company, Sanofi had very limited sales representative interaction with external customers over the remainder of 2020 due to Covid-19. The local representative did have contact with some of the diabetes specialists over the latter

half of 2020 and was aware that another diabetes specialist was keen to make a formulary application in Q4 2020.

Sanofi provided a copy of the Formulary Support Pack (Suliqua Formulary Support Pack and its associated briefing document (Suliqua Formulary Support Pack Briefing Document which were aligned with the current Suliqua indications. Sanofi noted that the briefing document instructed that provision of the formulary pack was on request and that Sanofi staff must not complete any NHS forms for the health professional nor edit the Suliqua Formulary Pack. However, there was no evidence presented by the complainant that Sanofi provided any support for the APC application(s).

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 was 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 local 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 positioning was set independently of Sanofi and there had not been any evidence discovered during Sanofi's internal investigation nor provided by the complainant that Sanofi had influenced or otherwise provided this positioning.

The complainant stated that they were notified of this formulary positioning but did not state whether this notification was by Sanofi or from another source. Without any identifiable details of the complainant, Sanofi could not examine if it had a record of a Sanofi interaction with this health professional. From Sanofi's broader investigations, 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. All promotional materials used would have been reviewed and certified to ensure consistency with the Suliqua licence. There was no evidence that Sanofi had breached 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.

As Sanofi's attention had been drawn to the local APC's Formulary position, Sanofi's medical department had proactively contacted the APC to advise them of the inconsistency between the SPC and the formulary positioning, noting that their listing was wholly independent of Sanofi. Sanofi received subsequent confirmation from the APC advising Sanofi that it had amended the Suliqua Entry. Sanofi provided a website screenshot of the amended text.

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 the complainant 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 the complainant's allegation that Suliqua was not licensed to be used with basal insulin as referred to in formulary position he/she was notified of. 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'.

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The Panel did not consider that the complainant had raised an allegation in relation to briefing. The Panel therefore ruled no breach of Clause 15.9.

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

Complaint received **6 March 2021**

Case completed **6 October 2021**