CASE AUTH/3559/9/21

ANONYMOUS v SANOFI

Alleged promotion of Toujeo and Suliqua by health professionals

An anonymous complainant who described him/herself as a company employee complained about one of Sanofi's business units (BU).

The complainant stated that he/she was a current employee of Sanofi and had become more and more concerned with the direction his/her BU was heading. Over the last 18 months or so there had been a clear driver to develop 'advocates' for Sanofi's brands (Toujeo (insulin glargine) and Suliqua (insulin glargine, lixisenatide)) – those health professionals who used Sanofi's products and were willingly to advocate them to their peers.

The complainant stated that this was normal in pharmaceuticals, however the way it had been briefed made many feel very uncomfortable. Firstly, the materials used had not been approved and constituted a briefing, with clear direction in both documents. Secondly, it was clear in the documents and in various internal conversations, for a health professional to become a DA (developing advocate) and then move to a MA (mobilising advocate), they must use either Toujeo or Suliqua. The health professional would be paid to advocate the products, which based on their qualification to become a mobilising advocate or a developing advocate, could be construed as an inducement to prescribe. There was a meeting in September 2021 with a speaker who had gone through this very process. Lastly, the complainant queried whether the health professionals in question were aware that their data was used in such a fashion and if this constituted a General Data Protection Regulation (GDPR) breach. The complainant stated that this had been raised internally by him/her and several colleagues to various members of the leadership team, all to no avail.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that one of its business units introduced the term 'developing advocate', for health professionals who were not established users of Sanofi products, and 'mobilising advocate' where advocacy already existed. Sanofi developed a 'Toujeo Advocacy Menu' which was an internal document that listed information on the health professional's expertise and experience with Toujeo; health professional's consent, via a certified form, was sought prior to adding them to the advocacy menu which included their biography and area of expertise.

The Panel noted Sanofi's submission that there were plans to develop an 'Advocacy Menu' for Suliqua in 2020 but this was not progressed, due to the Covid-19 pandemic. The Panel therefore only considered the arrangements in relation to Toujeo. The Panel noted Sanofi's submission about the timing and decided to make its rulings under the 2019 Code.

1 Toujeo brand advocates

The Panel considered that there were a number of potential concerns when pharmaceutical companies developed on going relationships with health professionals who were known prescribers of the company's medicines. There were requirements in the Code to that effect including the importance of being transparent about the relationships. It was not necessarily a breach of the Code to have such relationships. The difference here was that health professionals who were developed as advocates would be asked to present about Sanofi's products at meetings and would be paid to do so. This in itself was not necessarily a breach of the Code.

The Panel noted that there was no expectation that any health professional would definitely be asked to be a speaker. The Panel noted Sanofi's submission that the health professional would be paid for any presentation and that there were no fees for service associated with a health professional giving consent to be included within the 'Toujeo Advocacy Menu'.

The Panel did not consider that the complainant had established that becoming a Sanofi developing advocate or mobilising advocate would amount to an inducement to prescribe Sanofi's medicines as alleged and no breach of the 2019 Code was ruled.

The Panel noted that the complainant provided screenshots from a spreadsheet which he/she alleged was briefing material that had not been approved. The Panel noted Sanofi's submission that the spreadsheet included internal use templates which were to be used in line with training to support employees with local account planning which Sanofi did not consider required separate certification.

The Panel noted that the templates, at the top of the page, had steps to developing an advocate which included identifying an innovator who was willing to prescribe Suliqua/Toujeo in a few patients to gain experience to be followed up to encourage sharing with peers and the development of case studies to use at meetings. Staff were also instructed to ask if the health professional wished to become an advocate and if so a development plan was to be agreed before the health professional moved to becoming a MA.

Sanofi submitted that one member of each diabetes sales team was selected as an advocacy champion; the templates were to be used by these sales team members to support local account planning which instructed them to identify the innovators who were willing to prescribe Suliqua/Toujeo in a few patients to gain experience. In the Panel's view, it could not see how the material could be seen as anything other than representatives briefing material as set out in the 2019 Code. The Panel noted that the material had not been certified and a breach of the 2019 Code was ruled. The Panel ruled a further breach as the failure to recognise that the material at issue constituted briefing material that required certification meant that Sanofi had not maintained high standards.

2 Meeting

The Panel noted Sanofi's submission that the named health professional had never consented to, nor been included in the Toujeo Advocacy Menu and was contracted as an external expert and paid in line with fair market value. The Panel considered that the

complainant had not established that there was any evidence to show that the engagement of the named health professional, or the arrangements, were an inducement to prescribe a Sanofi medicine as alleged and no breach of the 2019 Code was ruled.

3 Alleged GDPR breach

The Panel noted Sanofi's submission that all health professionals listed in the 'Toujeo Advocacy Menu' provided their consent to be included using a certified consent form which explained how their data would be used. Sanofi submitted that it had investigated the matters raised by the complainant and had not identified any breaches of the UK GDPR.

The Panel noted that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to GDPR. The Panel did not consider that the complainant had established that Sanofi's activities with regards to the inclusion of health professionals' data within the 'Toujeo Advocacy Menu' had breached GDPR. Accordingly, no breach of the 2019 Code was ruled.

The Panel did not consider that the particular circumstances in this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. No breach of Clause 2 was ruled.

An anonymous complainant who described him/herself as a company employee complained about Sanofi's General Medicines business unit (BU).

COMPLAINT

The complainant stated that he/she was a current employee of Sanofi with several years' experience in the pharmaceutical industry, including as a representative. The complainant had become more and more concerned with the direction his/her BU (General Medicine) was heading. Over the last 18 months (approximately.) there had been a clear driver to develop 'advocates' for Sanofi's brands (Toujeo (insulin glargine) and Suliqua (insulin glargine, lixisenatide)) – those health professionals who used Sanofi's products and were willingly to advocate them to their peers.

The complainant stated that now this was [not] outside of the ordinary and was normal in pharmaceuticals, however the way it had been briefed made many feel very uncomfortable. Firstly, the materials used had clearly not been approved and constituted a briefing, with clear direction in both documents. Secondly, it was clear in the documents and in various internal conversations, for a health professional to become a DA (developing advocate) and then move to a MA (mobilising advocate), they must use either Toujeo or Suliqua. As a developing advocate or mobilising advocate, the health professional would be paid to advocate the products, which based on their qualification to become a mobilising advocate or a developing advocate, could be construed as an inducement to prescribe. There was a large scale meeting in September 2021 with a speaker who had gone through this very process. Lastly, the complainant queried whether the health professionals in question were aware that their data (name, prescribing habits, plans) was used in such a fashion and if this constituted a GDPR breach. The complainant stated that this had been raised internally by him/her and several of his/her colleagues to various members in the leadership team, all to no avail. It was therefore, with a heavy heart he/she had to raise this as a complaint.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 2, 3.4, 5.1, 8.1 and 24.2 of the 2021 Code.

RESPONSE

Sanofi UK noted that the complainant raised concerns related to activities within the Sanofi General Medicines Business Unit (BU) relating to advocacy development for Sanofi products. It was very concerned to receive such a complaint from someone who described themselves as a current employee and had carefully investigated the matters they had raised, being mindful to maintain anonymity of the complainant.

In Sanofi's response, it addressed the requirements of Clauses 2, 3.4, 5.1, 8.1, and 24.2 (in relation to the inducement provisions in the sixth bullet point) of the 2021 Code. Sanofi stated that it had however noted during its investigation that the activities in question were predominantly undertaken when either the 2016 or 2019 Codes were in operation.

Sanofi addressed the concerns as follows.

1 Brand advocates

Sanofi submitted that in 2018, the Sanofi General Medicines BU outlined an advocacy classification for health professionals in relation to use of Sanofi products. Terminology used, as stated by the complainant, was 'developing advocate' (DA) for health professionals who were not established users of Sanofi's products, and where advocacy existed the term 'mobilising advocate' (MA) was used. Developing advocacy for Sanofi products, as was standard practice across the industry, could involve a range of activities to legitimately promote Sanofi products to encourage usage in appropriate patients. Mobilising of advocates involved engaging customers who had experience of using the product in appropriate patients as expert speakers for Sanofi-led meetings with health professionals.

To support the development of advocates, one member of each Sanofi diabetes area sales team was selected to be an 'Advocacy Champion' for their area team. These 'Advocacy Champions' were provided with dedicated training on advocacy development. Training material was certified (SAGB.TJO.18.02.0137b) and used as a briefing for the sales area Advocacy Champions.

To support the 'mobilising of advocates', the head office diabetes professional relations team developed a 'Toujeo Advocacy Menu' which was an internal document that listed information about individual external expert health professionals with expertise on and experience using Toujeo who could be approached to speak at Sanofi-led meetings about this product. These health professionals had been asked if they were prepared to be included in this 'speaker bank'. If they agreed to participate, their agreement was confirmed using a certified consent form (SAGB.TJO.18.01.0086a), which outlined the data that would sit within this internal 'Toujeo Advocacy Menu' about that individual and how it would be used. The profiles of health professionals added to the 'Toujeo Advocacy Menu' included their biography and areas of expertise. There were no fees for service associated with their consent to be included within the 'Toujeo Advocacy Menu', nor any expectation that any particular health professional would definitely be asked to be a speaker. Any health professional who was included in this bank of potential speakers was someone Sanofi viewed as having the appropriate expertise to speak on

a particular specified topic. To have the necessary expertise to speak about Toujeo, the customer would need to be someone with existing experience of the product's use in appropriate patients. When new customers were identified as Toujeo advocates, the 'menu' was updated accordingly. Sanofi submitted that there were no inducements to prescribe, as alleged by the complainant. Participating health professionals were clear on the purpose of this internal document and aware that if they were approached as a potential speaker for an event there would be separate contracting for that particular event. Any payments for these contracted events would be in line with fair market value.

Sanofi stated that it refuted that its interactions with health professionals in relation to these activities provided inducements to prescribe, supply, administer, recommend, buy, or sell any medicine and therefore Sanofi refuted a breach of Clause 24.2 (in relation to the sixth bullet point).

The 'Toujeo Advocacy Menu' itself, after compilation, was certified before use (SAGB.TJO.18.01.0086b) and had an accompanying certified briefing document (SAGB.TJO.18.06.0888). These items were first used in June 2018 and were recertified whenever any updates were made. The 'Toujeo Advocacy Menu' was not used beyond 25 March 2020 and both the final version of the Toujeo Advocacy Menu (SAGB.TJO.18.01.0086b(7)) and its associated briefing document (SAGB.TJO.18.06.0888(7)) were withdrawn on 25 March 2020.

There were plans to develop a similar 'Advocacy Menu' for Suliqua in 2020. This sat within the 2020 marketing team's operational plan, but this was not progressed, due to the Covid-19-related environmental impact on activities with external customers.

The complainant had provided documents to support their complaint. Sanofi submitted it had attempted to identify the purpose and use of these documents.

a Sanofi submitted that the spreadsheets provided by the complainant in excel format were internal use templates to support the Advocacy Champions with local account planning. As account planning templates, to be used by the Advocacy Champions in line with their training, these templates were not viewed as requiring separate certification.

b Sanofi believed that the slide deck provided by the complainant was used in November 2020 by a Sanofi marketing manager to facilitate a discussion between themself and the Sanofi Advocacy Champions to gain their feedback to support development of the marketing team's operational plans for 2021. This feedback session was conducted as a Zoom call. Sanofi provided a copy of the slides that were used by the marketing manager, which showed on slide 4 the questions they raised with Advocacy Champions during this session. The slides were not used for briefing and therefore did not require certification.

Sanofi therefore refuted a breach of Clause 8.1 in relation to the use of these materials.

2 Meeting September 2021

Sanofi stated that the named health professionals was engaged to participate in a Sanofi-led meeting in September 2021 for specialist diabetes nurses (Head Office-led invite MAT-GB-2103418 v1.0). They were contracted as an external expert and paid in line with fair market value fees for this service.

Sanofi stated that its records confirmed that the named health professionals had never consented to, nor been included in, the 'Toujeo Advocacy Menu'.

Sanofi stated that it was only able to provide details of its engagements with this health professionals where permitted under data protection legislation. Bearing this in mind, Sanofi provided a summary of the Transfers of Value made by Sanofi to this health professionals in 2018 and 2020 which were within the time period relevant to complaint.

3 Alleged GDPR breach

Sanofi stated that as mentioned above, the development of advocates was standard practice across the industry and a common element of the promotion of medicines. Customers would also expect companies to retain a record of their interactions in order to carry out their business operations, including in this regard. In any event, the Sanofi Privacy Policy made clear that Sanofi might collect and use personal data relating to customers (such as their name, job title and place of work as well as information about how they used Sanofi's products and services), from interactions with them or from publicly available sources, in order to carry out Sanofi's business operations, including the marketing and sale of products. As also stated above, all health professionals listed in the 'Toujeo Advocacy Menu' provided their consent for their data to be included and used in this manner by completing a certified consent form which explained the data that would be included and the purposes for which it would be used. This 'speaker bank' was for internal use only. Sanofi also noted that the health professionals named by the complainant, as confirmed earlier, was not a participant in the 'Toujeo Advocacy Menu'.

In respect of the allegation of a breach of Clause 3.4, Sanofi noted that the PMCPA supervised the Code, which focussed on the promotion of medicinal products and related activities. It was not the competent authority for the purposes of codes, laws and regulations applicable to data privacy, and Sanofi respectfully suggested that the PMCPA might not properly make adverse findings in relation to these matters. Notwithstanding this, Sanofi had investigated the matters raised by the complainant and had not identified any breaches of the UK GDPR.

In summary, Sanofi was disappointed that these concerns had not been escalated internally. Sanofi did however believe that its promotional activities in relation to both development and mobilisation of advocates were compliant with the Code. Sanofi refuted breaches of Clauses 3.4, 8.1, and 24.2 (in relation to the inducement provisions in the sixth bullet point) and had not identified evidence that would indicate Sanofi had breached high standards (Clause 5.1) or brought the industry into disrepute (Clause 2). Sanofi stated that it similarly refuted any breaches of the equivalent provisions for these clauses in either the 2016 or 2019 Codes.

Sanofi requested that certain documents it had provided to support this case were not shared.

PANEL RULING

The Panel noted Sanofi's submission that its general medicines business unit introduced the term 'developing advocate', for health professionals who were not established users of Sanofi products, and 'mobilising advocate' where advocacy already existed. Sanofi submitted that to support the mobilising of advocates, it developed a 'Toujeo Advocacy Menu' which was an internal document that listed information on the health professional's expertise and experience

with Toujeo; health professional's consent, via a certified form, was sought prior to adding them to the advocacy menu which included their biography and area of expertise.

The Panel noted Sanofi's submission that there were plans to develop an 'Advocacy Menu' for Suliqua in 2020. This sat within the 2020 marketing team's operational plan, but this was not progressed, due to the Covid-19-related environmental impact on activities with external customers. The Panel therefore only considered the arrangements in relation to Toujeo. The Panel noted Sanofi's submission about the timing and that the applicable codes were 2016 and 2019 rather than 2021. The Panel noted that the case preparation manager referred to the 2021 Code, nonetheless the Panel decided to make its rulings under the 2019 Code.

1 Toujeo brand advocates

The Panel considered that there were a number of potential concerns when pharmaceutical companies developed on going relationships with health professionals who were known prescribers of the company's medicines. There were requirements in the Code to that effect including the importance of being transparent about the relationships. It was not necessarily a breach of the Code to have such relationships. The difference here was that health professionals who were developed as advocates would be asked to present about Sanofi's products at meetings and would be paid to do so. This in itself was not necessarily a breach of the Code.

The Panel noted that there was no expectation that any health professional would definitely be asked to be a speaker. The Panel noted Sanofi's submission that the health professional would be paid for any presentation they provided and that there were no fees for service associated with a health professional giving consent to be included within the 'Toujeo Advocacy Menu'.

The Panel did not consider that the complainant had established that becoming a Sanofi developing advocate or mobilising advocate would amount to an inducement to prescribe Sanofi's medicines as alleged and no breach of Clause 23.1 of the 2019 Code (which included some of the requirements of Clause 24.2 of the 2021 Code) was ruled.

The Panel noted that the complainant provided screenshots of tabs from an excel spreadsheet which he/she alleged was briefing material that had not been approved. The Panel noted Sanofi's submission that the spreadsheet included internal use templates which were to be used in line with training to support employees with local account planning which Sanofi did not consider required separate certification.

The Panel noted that the templates, at the top of the page, had steps to developing an advocate which included identifying an innovator who was willing to prescribe Suliqua/Toujeo in a few patients to gain experience to be followed up to encourage sharing with peers and the development of case studies to use at meetings. Staff were also instructed to ask if a health professional wished to become an advocate and if so a development plan was to be agreed before the health professional moved to becoming a MA.

Sanofi submitted that one member of each diabetes sales team was selected as an advocacy champion; the templates were to be used by these sale team members to support local account planning which instructed them to identify the innovators who were willing to prescribe Suliqua/Toujeo in a few patients to gain experience. In the Panel's view, it could not see how the material could be seen as anything other than representatives briefing material as set out in

Clause 15.9 of the 2019 Code (which was similar to Clause 17.9 of the 2021 Code). The Panel noted that the material had not been certified and a breach of Clause 14.1 of the 2019 Code (which was similar to Clause 8.1 of the 2021 Code) was ruled. The Panel considered that the failure to recognise that the material at issue constituted briefing material that required certification meant that Sanofi had not maintained high standards. A breach of Clause 9.1 of the 2019 Code (which was similar to Clause 5.1 of the 2021 Code) was ruled accordingly.

2 Meeting in September 2021

The Panel noted Sanofi's submission that the named health professional, a specialist diabetes nurse, had never consented to, nor been included in the Toujeo Advocacy Menu. He/she was contracted as an external expert and paid in line with fair market value. The Panel considered that the complainant had not established that there was any evidence to show that the engagement of the named health professional, or the arrangements, were an inducement to prescribe a Sanofi medicine as alleged and no breach of Clause 23.1 of the 2019 Code (which included some of the requirements of Clause 24.2 of the 2021 Code) was ruled.

3 Alleged GDPR breach

The Panel noted that the complainant queried whether the health professionals classed as advocates were aware that their data, ie name, prescribing habits and plans, were being utilised in this manner and queried whether this constituted a breach of GDPR.

The Panel noted Sanofi's submission that all health professionals listed in the 'Toujeo Advocacy Menu' provided their consent to be included using a certified consent form which explained how their data would be used. The Panel further noted Sanofi's submission that it had investigated the matters raised by the complainant and had not identified any breaches of the UK GDPR.

The Panel noted that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to GDPR. The Panel did not consider that the complainant had established that Sanofi's activities with regards to the inclusion of health professionals' data within the 'Toujeo Advocacy Menu' had breached GDPR. Accordingly, no breach of Clause 1.11 of the 2019 Code (which was similar to Clause 3.4 of the 2021 Code) was ruled.

The Panel did not consider that the particular circumstances in this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use. No breach of Clause 2 was ruled.

Complaint received **14 September 2021**

Case completed **6 June 2022**