CASE AUTH/3500/4/21 ***NO BREACH OF THE CODE***

COMPLAINANT v SANOFI

Representative training

An anonymous, non-contactable complainant complained about training Sanofi had provided him/her as a new diabetes representative.

The complainant stated that a lot of the training had been delivered/developed by a fellow representative. The complainant considered that the complex nature of the disease area and the products meant that all sessions should be delivered and developed by an experienced training lead and not by a fellow representative. The complainant stated that he/she believed that this did not maintain high standards nor supply adequate training or sufficient scientific knowledge to enable him/her to provide full and accurate information about the medicines. The complainant had raised the matter with his/her line manager to be told that the training was delivered in this way due to budget cuts/a lack of knowledge in the business unit. The complainant had never received such poor training. Many of the training sessions had been held remotely and therefore he/she could not send any physical evidence. It was more the delivery and lack of knowledge on display via the trainers. The complainant hoped the Panel could encourage the unit to re-run the training (with a reputable trainer), prior to any meetings with health professionals as he/she felt ill-equipped to hold calls with doctors and nurses in a safe, knowledgeable and informative manner.

The detailed response from Sanofi is given below.

The Panel noted that the anonymous, non-contactable complainant had not provided copies of any materials nor any details of when the training had taken place. The Panel noted that it was for the complainant to prove his/her complaint on the balance of probabilities.

The Code required representatives to be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. The Code did not stipulate who was to give that training, although clearly the training they provided must be such as to fulfil the requirements of the Code. The Panel noted that Sanofi referred to training given to newly appointed sales representatives in March and April 2021. Sanofi submitted that training was delivered by appropriately qualified members of staff with sufficient expertise in the relevant field. The staff involved included medical science liaisons (MSLs), some of the medical team and the brand team. The Panel noted Sanofi's submission that one representative was involved in the training in a co-ordinating, supportive capacity and that he/she had also provided support in practical sessions, contributing towards queries related to the use of sales aids in the field.

The Panel noted that the complainant had stated that the poor quality of the training meant that he/she felt ill-equipped to hold calls with doctors and nurses in a safe, knowledgeable and informative manner. The Panel noted, however, that in order to be validated to start promoting in the field, all representatives had to successfully pass all the validations and viva assessments and, in that regard, Sanofi had submitted that no representative would be 'ill-equipped to hold calls with any customer in a safe, knowledgeable and informative manner'.

The Panel further noted that the complainant had stated that he/she had raised the matter of training with his/her line manager and that Sanofi had randomly interviewed one area business manager within the business unit. That interview highlighted that there was no record of issues raised regarding the quality of the product training delivered to the representatives or of the poor quality of the training itself. No evidence of budgetary implications on the quality of the training was identified during the investigation. The Panel noted that as the complainant was anonymous, Sanofi would not know which area business manager was his/her line manager but, given what the line manager was alleged to have stated, it queried why the company had not interviewed all of the area business managers.

Nonetheless, the Panel noted its comments above, including the validation of representatives before they promoted products, and considered that the complainant had failed to show that, on the balance of probabilities, the delivery of the training offered was poor as alleged. The Panel did not consider that the complainant had shown that high standards had not been maintained; there was no evidence to suggest that those who delivered the training lacked the knowledge to do so. No breaches of the Code were ruled including no breach of Clause 2.

An anonymous, non-contactable complainant complained about training Sanofi had provided him/her as a new diabetes representative when he/she joined the company.

COMPLAINT

The complainant stated that he/she was concerned about some of the practises which were occurring at Sanofi; he/she had recently joined the organisation as a diabetes representative and was dismayed at the level of training he/she had received.

The complainant understood that the company had gone through a period of turbulence following an internal restructure, however, he/she felt this was no excuse for the levels of training he/she had received. The complainant stated that a lot of the training he/she had received had been delivered/developed by a fellow representative and not a training lead with extensive diabetes experience. This was no slur on the representative who had done this to the best of his/her abilities – however, he/she was not a recognised trainer and was not equipped/sufficiently knowledgeable to deliver these sessions. The complainant considered that the complex nature of this disease area and the products meant that all sessions should be delivered and developed by an experienced training lead and not by a fellow representative. The complainant stated that he/she believed that this did not maintain high standards nor supply adequate training or sufficient scientific knowledge to enable him/her to provide full and accurate information about the medicines he/she promoted. The complainant stated that he/she had raised the matter with his/her line manager to be told that the training was delivered in this way due to budget cuts/a lack of knowledge in the business unit. The complainant stated that

he/she had worked in the industry for several years and had never heard of this before nor received such poor training. Many of the training sessions had been held remotely and therefore he/she could not send any physical evidence. It was more the delivery and lack of knowledge on display via the trainers. The complainant stated that he/she hoped the Panel could encourage the unit to re-run the training (with a reputable trainer), prior to any meetings with health professionals as he/she felt ill-equipped to hold calls with doctors and nurses in a safe, knowledgeable and informative manner.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 15.1, 9.1 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 had conducted an internal investigation, which had included interviews with members of staff while taking particular care to protect the anonymity of the complainant. Sanofi did not consider that this had adversely affected its response and it was attempting to respond in full, given the limited information included in the original complaint.

Noting the lack of evidence provided, Sanofi stated that its response would address the points raised by the complainant based on the training program that the Sanofi Diabetes Franchise had delivered to newly appointed representatives in March and April 2021 (with focus on Toujeo and Lantus).

Training program materials and delivery schedule

Sanofi submitted that the program spanned over 6 weeks, was a combination of therapy area, product training, and brand strategy:

> **Week 1**: Following a general company induction day, six modules each of 2 hours which provided scientific insights on the disease area were delivered in a virtual classroom style over 4 days. The modules included:
>
> - Introduction to Diabetes (ref MAT-GB-2005427).
> - Impact of Diabetes (ref MAT-GB-2005428).
> - Diabetes Management (ref MAT-GB-2005429).
> - Non-insulin therapies (ref MAT-GB-2005430).
> - Insulin therapy (ref MAT-GB-2005431).
> - Landmark trials (ref MAT-GB-2004532).
>
> **Week 2**: This was a consolidation week with no planned activities, intended for representatives to familiarise themselves with the materials and information received in week 1.
>
> **Week 3**: There were 4 modules which focussed on product specific scientific insights and available supportive clinical data. Each module was delivered on separate days and all were structured in a similar way starting with a 2 hour virtual classroom session, followed by 1-4 hours' time for independent study allowing representatives to familiarise

themselves with the information received and ended with a 1 hour Q&A session in which any points of clarification or questions that needed elaboration, could be discussed. The modules included:

- Lantus (ref MAT-GB-2100701).
- Introducing Toujeo (ref MAT-GB-2100698).
- The Edition programme (ref MAT-GB-2100699).
- BRIGHT Study/Renal (ref MAT-GB-2001115).

Week 4: This week focussed on providing insight on the brand strategy, market dynamics tactics and customer journey and included training on the relevant sales aid and patient support program. Each module was delivered in a virtual classroom session of 1-1.5 hours generally followed by independent learning time of 2-2.5 hours which provided time for representatives to familiarise themselves with the content delivered during the session. During this week there were also virtual sessions for role plays, mainly centred around practising the use of the presented sales aid and leveraging the tactics and information received during the training. The modules included:

- Toujeo tactical plan 2021 (ref MAT-GB-2005010).
- Briefing Toujeo New starters training (ref MAT-IE-2100417)..
- Toujeo T1 Paed sales aid (ref MAT-GB-2003275)
- Briefing Toujeo T1 Paed sales aid (ref MAT-GB-2004664).
- T2 Bright & High risk sales aid (ref MAT-GB-2003274).
- Briefing T2 Bright & High Risk sales aid (ref MAT-GB-2004360).
- Toujeo Coach Internal training slides (ref MAT-GB-2101048).

Week 5: No scheduled activities were included. This time was assigned to the representatives to consolidate the information received in the previous weeks and to complete the relevant summary of product characteristics (SPC) online validation. These were assigned to the representatives via the online learning management system:

- Lantus SPC validation 2021 (ref MAT-GB-2100350).
- Toujeo SPC validation (ref MAT-GB-2001764).

Week 6: No scheduled activity was planned. This time was assigned to the representatives to consolidate all the information and training received during the previous weeks and was designated for self-study in preparation for the final viva and validation.

Sanofi submitted that all classroom style sessions were delivered via Zoom due to Covid-19 related circumstances. All relevant materials were made available to the representatives for consultation throughout the training programs. All materials were certified in PromoMats.

Sanofi stated that given the lack of evidence provided by the complainant, and taking particular care to protect the anonymity of the complainant, it had interviewed a random selection of representatives. There was an acknowledgment of the challenges related to attending the training in virtual settings, however, the consensus was that it did not have a significant impact on the overall quality of the training that was rated on an average of ‘8 out of 10’. The sessions as described above were delivered in full, the content and the time as described in the agenda was completely adhered to as consistently fed back by all the interviewees.

Sanofi believed that the training program materials and delivery schedule for representative in diabetes was robust and delivered in a professional, considerate manner.

Expertise that developed and delivered the training program

All sessions of the training were delivered by appropriately qualified members of staff with sufficient expertise in the relevant field.

- Weeks 1 and 3: The disease, scientific and clinical material was developed by medical science liaisons (MSLs) in collaboration with the head office medical team and exclusively delivered by MSLs.
- Week 4: The material relevant to product strategy and tactics was developed and delivered by the brand team.

Throughout the full program MSLs, brand leads and managers were contactable for the sales representatives to discuss any point of clarification, if required.

Sanofi stated that there was no evidence that representatives were involved in delivering any part of the training. One representative (with many years' experience as a diabetes representative) was involved in the training in a co-ordinating, and therefore supportive, capacity. In week 4, he/she also provided support in practical sessions where he/she contributed towards queries related to the use of sales aids in the field. This was all done with the brand team in the relevant sessions.

Sanofi believed that the training program was developed and delivered by a qualified, professional, expert team and therefore refuted the complainant's claim that a lot of the training was delivered/developed by a fellow representative and not a training lead with extensive diabetes experience and that the training did not maintain high standards nor supply adequate training or sufficient knowledge to enable him/her to provide full and accurate information of the medicine he/she promoted.

Validation of employees prior to engagement in the field

Sanofi noted that the complainant had alleged that the delivery and lack of knowledge on display via the trainers had led him/her to feel 'ill-equipped to hold calls with doctors and nurses in a safe, knowledgeable and informative manner'.

As outlined above, Sanofi believed that the training was a robust program delivered by a qualified, professional, expert team. However, prior to any representative engaging/promoting in the field, there was a validation step.

In addition to the relevant online SPC validation modules on the knowledge on the relevant products referenced above, ie Lantus SPC validation 2021 and Toujeo SPC validation, the competence of each representative who had gone through the program was also assessed finally via:

> Two role-plays validations which focused on gaining the competence of the representatives in promoting the relevant products in scenarios which were relevant to the product and business area where they would operate. Those were assessed by relevant members of the brand team:

- Toujeo Role-play validation (ref MAT-IE-2100586).
- Toujeo role-play validation brief (ref MAT-IE-2100587).

One viva assessment led and rated by the relevant MSL. The viva aimed at assessing the scientific knowledge and understanding of clinical data on the relevant product and disease area:

- VIVA validation form BRIGHT study (ref MAT-GB-2101523).
- VIVA validation form EDITION junior and meta-analysis (ref MAT-GB-2101502).

In order to be validated to start promoting in the field, the representatives had to successfully pass all the validations/viva described above. All materials used to support the validation process were certified separately.

Sanofi stated that the random selection of representatives which it had interviewed had joined the company at different times including two who recently joined and attended the induction training program that was rolled out in March and April 2021. All of the representatives interviewed considered that they were confident to carry out their role following the training and validation.

Sanofi thus considered that the training program delivered to representatives sufficiently equipped them with adequate training and scientific knowledge to enable them to provide full and accurate information about the medicines they provided. In addition, the robustness of the training and validation process demonstrated the maintenance of high standards by Sanofi and that no representative would be 'ill equipped to hold calls with any customer in a safe, knowledgeable and informative manner'.

Sanofi noted that the complainant also alleged that he/she raised the matter with his/her line manager to be told that the training was delivered in this way due to budget cuts/a lack of knowledge in the business unit. No evidence in support of the allegation was provided.

A randomly selected area business manager within the business unit was interviewed. The interview highlighted that there was no record of issues raised regarding the quality of the product training delivered to the representatives or of the poor quality of the training itself. No evidence of budgetary implications on the quality of the training was identified during this investigation.

Summary

Sanofi stated that the provisions of Clause 15.1 required that representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines that they promote.

On the basis of the internal investigation that was conducted, Sanofi considered that it had not only met the requirements of Clause 15.1 but had also maintained high standards in all the activities that had been conducted and delivered. This was seen in the delivery of the training including the training plan, the content of the training delivered by expert professionals and the assessment of the representatives following the training.

Sanofi denied breaches of Clauses 15.1, 9.1 or 2 of the 2019 Code.

PANEL RULING

The Panel noted that the anonymous complainant was non-contactable and so could not be contacted to provide further information. The complainant had made a number of comments regarding the quality of the training he/she had received but had not provided copies of any materials nor any details of when the training had taken place. The complainant had stated that as many of the training sessions had been held remotely, he/she could not send any physical evidence. However, he/she added that it was more the delivery and lack of knowledge on display via the trainers. The Panel noted that it was for the complainant to prove his/her complaint on the balance of probabilities.

The Panel noted that the Code required representatives to be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. The Code did not stipulate who was to give that training, although clearly the training they provided must be such as to fulfil the requirements of the Code. The Panel noted that Sanofi referred to training given to newly appointed sales representatives in March and April 2021. Sanofi submitted that training was delivered by appropriately qualified members of staff with sufficient expertise in the relevant field. The staff involved included MSLs, some of the medical team and the brand team. The Panel noted Sanofi's submission that one experienced representative was involved in the training in a co-ordinating, supportive capacity and that he/she had also provided support in practical sessions, contributing towards queries related to the use of sales aids in the field.

The Panel noted that the complainant had stated that the poor quality of the training meant that he/she felt ill-equipped to hold calls with doctors and nurses in a safe, knowledgeable and informative manner. The Panel noted, however, that in order to be validated to start promoting in the field, all representatives had to successfully pass all the validations and viva assessments and, in that regard, Sanofi had submitted that no representative would be 'ill-equipped to hold calls with any customer in a safe, knowledgeable and informative manner'.

The Panel further noted that the complainant had stated that he/she had raised the matter of training with his/her line manager to be told that the training was delivered as it was due to budget cuts/a lack of knowledge in the business unit. In that regard, the Panel noted that Sanofi had randomly interviewed one area business manager within the business unit. That interview highlighted that there was no record of issues raised regarding the quality of the product training delivered to the representatives or of the poor quality of the training itself. No evidence of budgetary implications on the quality of the training was identified during the investigation. The Panel noted that as the complainant was anonymous, Sanofi would not know which area business manager was his/her line manager but, in that regard, given what the line manager was alleged to have stated, it queried why the company had not interviewed all of the area business managers.

Nonetheless, the Panel noted its comments above, including the validation of representatives before they promoted products, and considered that the complainant had failed to show that, on the balance of probabilities, the delivery of the training offered was poor as alleged. No breach of Clause 15.1 was ruled. The Panel did not consider that the complainant had shown that high standards had not been maintained; there was no evidence to suggest that those who delivered the training lacked the knowledge to do so. No breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

Complaint received	**6 April 2021**
Case completed	**17 August 2021**