CASE AUTH/3166/2/19

COMPLAINANT v SANOFI

Alleged promotion of Epilim on Twitter

A complainant who described him/herself as a concerned UK health professional, complained about a tweet sent by Sanofi UK. The tweet referred to Epilim (sodium valproate) and read:

> **'Today we spoke @IMMDSReview [the Independent Medicines and Medical Devices Safety Review]. We have fully engaged in assisting the Review team to consider the complex issue arising from the use of Epilim to treat women and girls of child-bearing potential suffering from epilepsy.'**

Epilim was indicated for the treatment of generalized, partial or other epilepsy. The summary of product characteristics (SPC) stated that for female children and women of childbearing potential, valproate must be initiated and supervised by a specialist experienced in the management of epilepsy. Valproate should not be used in female children and women of childbearing potential unless other treatments were ineffective or not tolerated. Further information was provided in a number of sections of the SPC including that every effort should be made to switch female children to alternative treatment before they reached adulthood.

The complainant noted that Epilim (sodium valproate) had a black triangle. The tweet included the brand name and the indication which was likely to attract interest in the use of Epilim in patients. The complainant alleged that as this was a promotional item sent out by the official Sanofi Twitter account, it was quite a serious matter and Clauses 2 and others needed to be addressed. The complainant noted that Twitter reached massive audiences extremely quickly and had the ability to do vastly more damage than traditional advertisements in medical journals and yet it appeared that much less care was taken.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that the tweet at issue contained material of general public interest; in the Panel's view, it was highly likely that Sanofi's Twitter followers would include members of the public. The Panel further noted that the nature of Twitter was such that tweets could be broadly and quickly disseminated in the public domain. When material was available to the public it needed to comply with the relevant requirements of the Code. Members of the public would include health professionals. There was no submission from Sanofi that the tweet was restricted in any way.

In the Panel's view, the tweet was not intended as advertising for a health professional audience and therefore the allegations relating to the promotion to health professionals were not relevant. The Panel ruled no breach in relation to these allegations. The Panel considered that as a general matter it was not necessarily a breach of the Code to tweet information to the public and some people would be interested in the ongoing safety review. The complainant had not provided any information to show that the public would not be interested in the information. Conversely, Sanofi submitted that the review had been established to examine concerns raised by patients and families, ie the public. The Panel considered all the circumstances including that the complainant had not met the burden of proving his/her complaint on the balance of probabilities in this regard and ruled no breach.

The Panel did not consider that the tweet amounted to disguised promotion. The company name, the name of the medicine and its indication were given. In the Panel's view, the general public would not be misled into thinking the nature of the tweet was disguised. This requirement was generally relevant when material for health professionals was disguised promotional material. The Panel ruled no breach of the Code.

In relation to the allegations about certification, the Panel considered that the tweet should have been certified. It related to a medicine and was intended for the public and a breach was ruled. The Panel ruled no breach in relation to the requirement to certify promotional material for health professionals.

The Panel noted the submission from Sanofi regarding its arrangements for training. In the Panel's view, the ruling of a breach of the Code did not in itself mean that a company had not met the training requirements. The Panel considered that the complainant had not proved, on the balance of probabilities, that a breach had occurred.

The Panel was concerned that the tweet did not explain that the review related to the adverse effects of sodium valproate – of which Epilim was one brand. Nor did the tweet reflect the important safety information in the current Epilim SPC regarding the cautions for the use of valproate in female children and women of childbearing potential. No explanation was given of the 'complex issue arising' from the use of Epilim in that patient group. Some readers might be left with the impression that there were no restrictions on the use of Epilim; insufficient information was provided in order for readers to understand the significance of, and the reason for, the review. In the Panel's view, the tweet did not give a balanced view and, in that regard, was misleading about the ongoing safety review and the use of the medicine; it might raise unfounded hopes of successful treatment. The Panel therefore ruled a breach of

the Code. The Panel noted that the complainant raised a general point about safety, referring to the use of the black triangle. The Panel considered that its ruling of a breach covered the general allegation referring to the use of the black triangle.

The Panel noted that the tweet named a prescription only medicine (Epilim) and referred to its use (in epilepsy). In that regard, the Panel considered that, on balance, a prescription only medicine had been advertised to the public and ruled a breach of the Code.

The Panel also ruled a breach as high standards had not been maintained.

The Panel noted that the tweet linked to @IMMDSReview. It considered that it would be clear to readers that this was the IMMDS Review Twitter handle and not a Sanofi site. The Panel therefore ruled no breach of the requirement to be clear when leaving a company site.

The Panel noted its rulings and comments above but did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure.

A complainant who described him/herself as a concerned UK health professional, complained about a tweet sent by Sanofi UK. The tweet referred to Epilim (sodium valproate) and read:

> 'Today we spoke @IMMDSReview [the Independent Medicines and Medical Devices Safety Review]. We have fully engaged in assisting the Review team to consider the complex issue arising from the use of Epilim to treat women and girls of child-bearing potential suffering from epilepsy.'

Epilim was indicated for the treatment of generalized, partial or other epilepsy. The summary of product characteristics (SPC) stated that for female children and women of childbearing potential, valproate must be initiated and supervised by a specialist experienced in the management of epilepsy. Valproate should not be used in female children and women of childbearing potential unless other treatments were ineffective or not tolerated. Further information was provided in a number of sections of the SPC including Section 4.3 Contraindications, Section 4.4, Special warnings and precautions for use where detailed information was provided about the use of the medicine in females including details of the pregnancy prevention programme and Section 4.6 Fertility, pregnancy and lactation. The SPC stated that prescribers must ensure that every effort should be made to switch female children to alternative treatment before they reached adulthood.

COMPLAINT

The complainant noted that Epilim (sodium valproate) had a black triangle. The tweet included the brand name and the indication which was likely to attract interest in the use of Epilim in patients. The complainant alleged that as this was a promotional item sent out by the official Sanofi Twitter account, it was quite a serious matter and Clauses 2, 4.1, 4.2, 4.3, 4.4, 4.9, 9.1, 9.9, 11.1, 12.1, 14.1, 14.5, 16.1, 26.1, 26.2, 28.1 and 28.6 needed to be addressed. The complainant acknowledged that this was a long list of clauses but unless they were mentioned they could not be reviewed by the Panel. The complainant noted that Twitter reached massive audiences extremely quickly and had the ability to do vastly more damage than traditional advertisements in medical journals and yet it appeared that much less care was taken.

Sanofi was advised that the complaint would be considered under the 2019 Code.

RESPONSE

Sanofi noted that the complaint was sent by email on 27 February 2019 and referred to a tweet published on Sanofi UK's Twitter account on 18 January 2019. The tweet reported on Sanofi's co-operation with the Independent Medicines and Medical Devices Safety (IMMDS) Review, directed by the Secretary of State for Health and Social Care and chaired by Baroness Cumberlege.

The IMMDS Review was a parliamentary review established to consider concerns raised by patients and families about three medical interventions, including sodium valproate, supplied as Epilim by Sanofi UK and as various different brands by other companies. The review's consideration of sodium valproate focussed on its use, principally as a treatment for epilepsy, in women and girls of child-bearing potential in view of the association with congenital malformations and developmental abnormalities in children exposed in utero.

Sanofi had provided substantial written material to assist the review in its consideration of sodium valproate in general and, in circumstances where Sanofi had knowledge only of its own product, Epilim in particular. On 18 January 2019, four Sanofi representatives provided oral evidence to the review and answered questions specifically about the supply of Epilim in the UK, the information provided in the product information for Epilim and the risk minimisation activities and materials directed and approved by the regulatory authorities and distributed by Sanofi UK.

The tweet at issue was published after the Sanofi representatives had appeared before the review. The public importance of the review and the public interest in the co-operation of relevant stakeholders with its work in the context of patient safety required no explanation. The tweet was issued in this context to confirm Sanofi's commitment to assisting the review in its consideration of these difficult issues. There was no intent to promote Epilim and the tweet did not do so. Sanofi submitted that the complaint was based on the incorrect premise that the tweet was promotional.

Clause 1.2 stated that promotion did not include various activities and material including:

- Factual, accurate, informative announcements and reference material concerning licensed medicines … provide they include no product claims;
- Summaries of product characteristics;
- Risk minimisation material; and
- The labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned ….'

Sanofi submitted that the tweet in question was a factual, informative announcement on a matter of public interest. Sanofi noted that the complainant claimed that there were two references in the tweet, which he/she seemingly construed demonstrated a promotional intent: (i) an indication for use; and (ii) use of the brand name. However, both of these elements were required for useful communication about a matter of public importance and did not, in the particular circumstances of the tweet, constitute promotion:

i. The reference to treatment of women and girls of child-bearing potential did not promote the use of Epilim in this patient population, but instead highlighted the difficulties of therapy in this patient group. The wording reflected and explained the purpose of the review and why Sanofi had been asked to give oral evidence on its product and the information provided in the product information for Epilim (and not the other generic sodium valproate products).

ii. Use of a brand name did not establish a promotional intent. In this case, the use of the brand name in the tweet was appropriate and non-promotional, because the announcement described Sanofi's co-operation with the review and the evidence it gave during the oral hearing, in circumstances where Sanofi's evidence focused upon the supply of Epilim and the development of information provided with Epilim, rather than generic sodium valproate.

In circumstances where the tweet was non-promotional, the substance of the complaint fell away and most of the identified clauses of the Code were not applicable.

Sanofi noted that Clauses 4.1, 4.2, 4.3, 4.4 and 4.9 addressed requirements for supply of prescribing information, non-proprietary name and an adverse event statement in all promotional material. Sanofi submitted that for the reasons explained above, the tweet was not promotional and the identified provisions did not apply and were not breached.

Sanofi stated that the messages on its Twitter account were seen only by those who had communicated a positive decision to 'follow' Sanofi or who otherwise elected to access the account. The tweet at issue contained material of general public interest.

For the reasons explained above, Sanofi stated that the tweet was non-promotional and fell outside the scope of the Code. There was no breach of Clause 11.1. As the tweet was not promotional and could not, therefore, be characterised as disguised promotion, there was no breach of Clause 12.1.

Sanofi stated that its social media policy required that all content of social media channels (including tweets) was approved in accordance with appropriate Code requirements, applicable policies and standard operating procedures (SOPs). However, as the tweet was non-promotional and did not fall within the scope of Clause 14.1 or the non-promotional activities identified in Clause 14.3, there was no requirement to certify it in accordance with Clause 14 and the complainant had provided no evidence to indicate a breach of Clause 14.1 or Clause 14.3.

The social media policy also provided that the content of all social media channels (including Sanofi UK's Twitter account) was the responsibility of the relevant channel owner, who had to ensure that appropriate approval procedures were followed. All Sanofi UK social media accounts were password controlled and content could be added only by authenticated users.

Sanofi explained that its training requirements in relation to the Code were set out in a policy. All Sanofi personnel were required to be trained on the general principles of the Code, repeated annually, and to demonstrate competence by achieving a satisfactory score in their responses to mandatory questions. More senior staff, including all of those concerned in any way with the preparation of material or activities covered by the Code were required to participate in and pass comprehensive in-house training on the relevant legal requirements and Code provisions. This training incorporated the requirements for promotion via electronic methods and social media. Following the initial programme, continuing training was undertaken to ensure that competence was maintained and updated.

The information in the tweet at issue related only indirectly to prescription only medicines; it was principally focussed on the independent review directed by Government. To the extent that it did constitute information 'about' prescription only medicines, it fell within the description of 'factual and balanced' material of public interest. The tweet was non-promotional and clearly did not encourage members of the public to request a specific prescription only medicine; rather it highlighted Sanofi's co-operation with the consideration of safety-related concerns raised by patients. Sanofi denied a breach of Clauses 26.1 or 26.2.

Sanofi reiterated that the tweet was non-promotional and was not subject to the Code. There was accordingly no breach of Clause 28.1 and the complainant had provided no evidence suggesting otherwise. The reference to Clause 28.6 was not understood. The tweet was published on a Sanofi sponsored Twitter account and included no link to any other site.

Sanofi submitted that the tweet notified followers of its Twitter account and those who chose to access the account of a factual matter of public importance. The tweet fell outside the scope of the Code.

In these circumstances, there was no basis for any finding that Sanofi had not maintained high standards. Sanofi stated that it had not breached relevant provisions of the Code, comprehensive policies were in place, and were followed and these policies were regularly updated and monitored in order to ensure that the company did not fall below standards required by the applicable legislation and the Code. Sanofi denied a breach of Clause 9.1.

Sanofi stated that as explained above, the tweet did not constitute an activity or material associated with promotion and fell outside the scope of the Code; the company denied a breach of Clause 2.

Sanofi stated in conclusion that the complaint was based on the incorrect assumption that the tweet was promotional; it was instead a non-promotional, factual announcement on a matter of public interest and therefore it fell outside the scope of the Code. In these circumstances, the clauses of the Code cited by the complainant were irrelevant and/or the complainant had submitted no evidence of breach.

PANEL RULING

The Panel noted that the use of social media including Twitter to provide information to the public was a legitimate activity for pharmaceutical companies as long as the material complied with the Code, particularly Clause 26.

The Panel noted Sanofi's submission that the tweet at issue contained material of general public interest; in the Panel's view, it was highly likely that Sanofi's Twitter followers would include members of the public. The Panel further noted that the nature of Twitter was such that tweets could be broadly and quickly disseminated in the public domain. When material was available to the public it needed to comply with the relevant requirements of the Code. Members of the public would include health professionals. There was no submission from Sanofi that the tweet was restricted in any way.

In the Panel's view, the tweet was not intended as advertising for a health professional audience. The Panel therefore considered that the allegations relating to the promotion to health professionals were not relevant. The Panel ruled no breach of Clauses 4.1, 4.2, 4.3, 4.4, and 4.9 of the Code. Similarly, the need to obtain prior permission before sending out the tweet did not apply to material for the public and no breach of Clause 9.9 was ruled.

The Panel considered that as a general matter it was not necessarily a breach of the Code to tweet information to the public and some people would be interested in the ongoing safety review. The complainant had not provided any information to show that the public would not be interested in the information. Conversely, Sanofi submitted that the review had been established to examine concerns raised by patients and families, ie the public. The Panel considered all the circumstances including that the complainant had not met the burden of proving his/her complaint on the balance of probabilities in this regard. The Panel ruled no breach of Clause 11.1.

The Panel did not consider that the tweet amounted to disguised promotion. The company name, the name of the medicine and its indication were given. In the Panel's view, the general public would not be misled into thinking the nature of the tweet was disguised. This requirement was generally relevant when material for health professionals was disguised promotional material. The Panel ruled no breach of Clause 12.1.

In relation to the allegations about certification, the Panel considered that the tweet should have been certified. It related to a medicine and was intended for the public. Certification of material for the public was covered by Clause 14.3. The company acknowledged that the tweet had not been certified. Sanofi had not met the requirements of Clause 14.5 as alleged and a breach was ruled by the Panel. The Panel ruled no breach of Clause 14.1 as the tweet was not promotional material for health professionals.

The complainant had not provided any detail or evidence regarding the alleged breach of Clause 16.1. The Panel noted the submission from Sanofi regarding its arrangements for training staff. In the Panel's view, the ruling of a breach of the Code did not in itself mean that a company had not met the training requirements set out in Clause 16.1. The Panel considered that the complainant had not proved, on the balance of probabilities, that a breach of Clause 16.1 had occurred and no breach was ruled.

The Panel was concerned that the tweet did not explain that the review related to the adverse effects of sodium valproate – of which Epilim was one brand. Nor did the tweet reflect the important safety information in the current Epilim SPC regarding the cautions for the use of valproate in female children and women of childbearing potential. No explanation was given of the 'complex issue arising' from the use of Epilim in that patient group. Some readers might be left with the impression that there were no restrictions on the use of Epilim; insufficient information was provided in order for readers to understand the significance of, and the reason for, the review. In the Panel's view, the tweet did not give a balanced view and, in that regard, was misleading about the ongoing safety review and the use of the medicine; it might raise unfounded hopes of successful treatment. The Panel therefore ruled a breach of Clause 26.2 of the Code. The Panel noted that the complainant raised a general point about safety, referring to the use of the black triangle. This was covered by Clause 26.3 in relation to material for patients taking the medicine. However, the tweet was not specifically for patients taking Epilim. The Panel considered the general allegation referring to the use of the black triangle was covered by its ruling of a breach of Clause 26.2.

The Panel noted that the tweet named a prescription only medicine (Epilim) and referred to its use (in epilepsy). In that regard, the Panel considered that, on balance, a prescription only medicine had been advertised to the public and ruled a breach of Clause 26.1 of the Code.

The Panel noted its rulings above and considered that high standards had not been maintained. It therefore ruled a breach of Clause 9.1 of the Code.

The Panel noted that Clause 28.1 stated that promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code. The Panel ruled no breach of this clause given its decision that the material was for the public as set out in its rulings of breaches of Clauses 26.1 and 26.2 above.

The Panel noted that Clause 28.6 stated that it should be made clear when a user was leaving any of the company's sites, or sites sponsored by the company, or was being directed to a site which was not that of the company. The Panel noted that the tweet linked to @IMMDSReview. It considered that it would be clear to readers that this was the IMMDS Review Twitter handle and not a Sanofi site. The Panel therefore ruled no breach of Clause 28.6.

The Panel noted its rulings and comments above but did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

Complaint received **27 February 2019**

Case completed **11 June 2019**