NO BREACH OF THE CODE

CASE AUTH/3467/2/21

ANONYMOUS GP v PFIZER

Conduct of a representative

An anonymous, non-contactable complainant who described him/herself as a GP, complained about the promotion of Eliquis (apixaban) by a named Pfizer Limited representative. Eliquis was an anticoagulant indicated for the prevention and treatment of certain thromboembolic events.

The complainant alleged that the representative had disparaged rivaroxaban (marketed as Xarelto by Bayer plc) and claimed that Eliquis had better safety and therefore should be used to address mortality in primary care.

The complainant stated that the quality of representatives had declined which he/she attributed to a lack of training. Any safety data must be balanced and understood by the representative and the complainant alleged an impact on patient safety.

The detailed response from Pfizer is given below.

The Panel noted that the complainant had provided the name of the representative but insufficient information so that the particular circumstances could be clearly identified. Pfizer had identified a possible short conversation that might have led to the complaint. The Panel noted that the representative estimated that the conversation lasted approximately 1.5 minutes.

The Panel noted that while both parties agreed that the representative had referred to both Eliquis and Xarelto, they had differed as to the details of the conversation; it was difficult in such cases to know exactly what had transpired. The complainant alleged that the representative had unfavourably compared Eliquis with Xarelto with regard to safety and stated that because Eliquis had better safety, it therefore should be used to address mortality in primary care. Pfizer had submitted that the representative had noted that NOACs appeared to be widely used in the practice, particularly rivaroxaban, and had only briefly referred to the key outcome data from Granger *et al*, which had compared Eliquis and warfarin.

The Panel considered that there might have been some confusion as the representative indicated that after he/she had referred to Xarelto use at the practice, he/she had then referred to outcome data from Granger *et al* which showed a reduction for Eliquis vs warfarin in stroke/systemic embolism, major bleeding and all-cause mortality. The representative stated no other data or claims were made. The Panel queried whether the GP, in such a short exchange, had instead thought that the differences referred to were between Eliquis and Xarelto. It appeared to the Panel that neither the account from the

representative nor the submission from Pfizer were clear that the comparator in Granger *et al* was warfarin.

The training agenda and brief details provided by Pfizer did not appear to put undue emphasis on the side effects of Xarelto.

A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint and that the Panel could not contact the complainant for more information. The complainant bore the burden of proof and had to establish his/her case on the balance of probabilities. The Panel did not consider that the complainant had established his/her case that the representative had disparaged Xarelto as alleged and there was no evidence that high standards had not been maintained nor that there was a direct impact on patient safety as alleged. No breach of the Code was ruled including Clause 2

An anonymous, non-contactable complainant who described him/herself as a GP, complained about the promotion of Eliquis (apixaban) by a named Pfizer Limited representative. Eliquis was an anticoagulant indicated for the prevention and treatment of certain thromboembolic events.

COMPLAINT

The complainant alleged that the representative had disparaged rivaroxaban (marketed as Xarelto by Bayer plc). The representative had compared the two medicines and claimed that Eliquis had better safety and therefore should be used to address mortality in primary care.

The complainant stated that he/she was a GP working in a named English county who had been a partner for a number of years and that the quality of representatives had declined which he/she attributed to a lack of training. The complainant submitted that he/she would like to think that the highest standards of ethics in the NHS were adhered to and expected representatives to do the same. The complainant stated that any safety data must be balanced and understood by the representative. The complainant considered that the matter in question could directly impact patient safety.

When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 2, 7.2, 9.1, 15.1 and 15.2 of the Code.

RESPONSE

Pfizer submitted that the representative identified by the complainant completed training on Eliquis in non-valvular atrial fibrillation (NVAF) on 9 October 2020. An interview with the representative had been conducted. Given the recent completion of training, the representative had a very limited number of interactions within the timeframe relevant to the complaint. An interaction with a GP on 18 November 2020 had been identified as the only Eliquis-related conversation that the representative had with a GP that included reference to rivaroxaban and data for Eliquis in the time between completion of product training and the end of November 2020. As the complainant's letter was dated 'Nov 2020', that seemed the only possible source of the complaint. The GP identified by the representative was based at a practice in a named county which was consistent with the information provided in the complaint.

Pfizer submitted that the call identified as the likely subject of this complaint was a telephone call made by the GP to the representative in November 2020. The day before the representative telephoned the main reception of the GP practice, identified him/herself by name and company and asked to speak with the GP, the GP was not available and so a message was left for the GP requesting a telephone call. The GP called the representative the next day, the call was brief, lasting approximately 90 seconds, was a verbal exchange, without any videoconferencing facilities and thus no materials were used. The representative recalled raising two topics with the GP during the brief conversation.

The first topic related to whether there would be an opportunity to present to the GP and relevant members of the primary care network (PCN) regarding the 'Detect, Protect, Perfect' (DPP) agenda (DPP referred to atrial fibrillation priorities within the NHS for diagnosis (detect), provision of anticoagulation in appropriate patients (protect) and ensuring anticoagulation was adequate (perfect)). The GP stated that there were other priorities within the PCN so declined to take that further.

A second topic was then raised by the representative who noted that novel oral anticoagulants (NOACs) appeared to be widely used in the practice, particularly rivaroxaban. The representative enquired whether an opportunity to present the data for apixaban, from the Aristotle trial (apixaban vs warfarin in patients with atrial fibrillation (Granger *et al* 2011)), could be arranged. The representative quoted the key endpoint data from the study which showed a reduction of 21% for stroke and systemic embolism, 33% [sic this should be 31%] for major bleeding and 11% for all-cause mortality. The GP, however, informed the representative that he/she should contact a colleague at the GP practice who was responsible for meetings with representatives. That concluded the telephone conversation. No other data was discussed with the GP during the brief telephone call and materials were not used. No comparative data or content comparing Eliquis and Xarelto was raised by the representative during the brief telephone conversation. A copy of a written statement from the representative was provided.

The Aristotle study (Granger *et al)* referred to during the telephone call was the phase 3 pivotal study for Eliquis vs warfarin and was the basis for the indication for prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) with one or more risk factors. Given the significance of that data, it was included within the Eliquis summary of product characteristics (SPC) in Section 5.1 (copy provided) and was covered extensively in the representative training, including as pre-learning material, pre-work assignments and data training presentations and workshops (copy of training material and agenda provided).

With regard to Clause 7.2, Pfizer submitted that when interviewed, the representative recalled quoting the key endpoint data from the Aristotle study. The data quoted were the percentage reductions from the hazard ratios – 'a reduction vs warfarin of 21% for stroke and systemic embolism, 33% [sic, this should be 31%] for major bleeding and 11% for all-cause mortality', which was consistent with the Eliquis SPC. The representative denied making any comparisons with Xarelto. On that basis, Pfizer considered that the data quoted to the GP were accurate and not misleading regarding the efficacy and safety profile for Eliquis and Pfizer therefore denied a breach of Clause 7.2.

With regard to Clause 15.1, Pfizer stated that between 28 September and 9 October 2020, the representative completed 24 hours of training on Eliquis for NVAF. A copy of a detailed overview of the training programme for the Eliquis NVAF indication was provided. Details of the representative's successful completion and understanding of the training course was evidenced

with scores provided for the Eliquis SPC examination undertaken in October 2020 and in the Eliquis NVAF final examination completed in October 2020. The representative had demonstrated both in the formal training course examinations and the interview conducted as part of Pfizer's response to this complaint, that he/she knew and understood the data and disease area for Eliquis and could appropriately provide full and accurate information about Eliquis in his/her promotional interactions. Pfizer provided a brief description of the representative's experience and qualifications and submitted that he/she had a demonstrated ability to understand scientific concepts and data. Given the representative's qualifications, experience and training, Pfizer denied a breach of Clause 15.1.

With regard to Clause 15.2, Pfizer submitted that the representative diligently and successfully completed the Eliquis training course. When contacting the GP practice, the representative appropriately identified his/herself and respectfully left a message for the GP that the GP chose to respond to. The representative accurately described the key data for Eliquis and did not make any inappropriate comparisons. Pfizer could see no evidence that the representative had failed to maintain high standards and it therefore denied a breach of Clause 15.2.

Pfizer submitted that its representative training course for promotion of Eliquis in NVAF was comprised of over 24 hours of training on the medicine and current management of the associated disease area. That comprehensive training and assessment process ensured that representatives were appropriately equipped to promote Eliquis. Upon interview, the representative provided a clear account of the interaction with the GP in November 2020 and he/she denied making any comparisons between Xarelto and Eliquis. The representative accurately provided data from the Eliquis pivotal study that he/she was fully trained on. During the interview, the representative described how he/she had contacted the practice, transparently provided his/her name and company details by telephone and left a clear, respectful message for the GP who then decided to return the call. Based on that, Pfizer believed it had upheld the high standards expected of the industry and had not brought discredit upon, or reduced confidence in, the industry. Pfizer, therefore, strongly denied breaches of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. 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 complainant had provided the name of the representative but insufficient information so that the particular circumstances could be clearly identified. Nonetheless, the complainant, who could not be contacted for further information, had stated where in the UK he/she practised; this information had been given to Pfizer and it had identified a possible short conversation that might have led to the complaint. The Panel noted that the representative estimated that the conversation lasted approximately 1.5 minutes in which the 'Detect, Protect, Perfect' agenda was discussed before the conversation moved on to Eliquis.

The Panel noted that while both parties agreed that the representative had referred to both Eliquis and Xarelto, they had differed as to the details of the conversation; it was difficult in such cases to know exactly what had transpired. The complainant alleged that the representative had unfavourably compared Eliquis with Xarelto with regard to safety and stated that because Eliquis had better safety, it therefore should be used to address mortality in primary care. Pfizer had submitted that the representative had noted that NOACs appeared to be widely used in the

practice, particularly rivaroxaban and had only briefly referred to the key outcome data from Granger *et al,* which had compared Eliquis and warfarin.

The Panel considered that there might have been some confusion as the representative's signed statement indicated that after he/she had referred to Xarelto use at the practice, he/she had then referred to outcome data from Granger *et al* which showed a reduction for Eliquis vs warfarin of 21% in stroke/systemic embolism, a 31% reduction in major bleeding and an 11% reduction in all-cause mortality. The representative had stated in his/her statement that other than that data/information, no other data or claims were made. The Panel queried whether the GP, in such a short exchange, had instead thought that the differences referred to were between Eliquis and Xarelto. It appeared to the Panel that neither the account from the representative nor the submission from Pfizer were clear that the comparator in Granger *et al* was warfarin.

The training agenda and brief details provided by Pfizer referred to data about Eliquis and its competitors including Xarelto. There did not appear to be undue emphasis placed on the side effects of Xarelto.

A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint and that the Panel could not contact the complainant for more information. The Panel further noted that the complainant bore the burden of proof and had to establish his/her case on the balance of probabilities. The Panel did not consider that the complainant had established his/her case that the representative had disparaged Xarelto as alleged and therefore ruled no breach of Clauses 7.2, 15.1 and 15.2 of the Code. The Panel also ruled no breach of Clause 9.1 and 2 as there was no evidence that high standards had not been maintained nor that there was a direct impact on patient safety as alleged.

Complaint received **3 February 2021**

Case completed **2 July 2021**