

CASE AUTH/3507/5/21 and Case AUTH/3513/5/21

COMPLAINANT v DAIICHI-SANKYO

Promotion of Lixiana (edoxaban)

An anonymous complainant who was originally contactable but later became non-contactable complained about the promotion of Lixiana (edoxaban).

Lixiana (edoxaban) was indicated, *inter alia*, in prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAf) with one or more risk factors, such as congestive heart failure, hypertension, age \geq 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).

The complainant submitted two separate complaints: Case AUTH/3507/5/21 and Case AUTH/3513/5/21. The case preparation manager decided to amalgamate the two cases as they were based on essentially similar evidence, in accordance with Paragraph 5.1 of the Constitution and Procedure.

Case AUTH/3507/5/21

The complainant stated that the Lixiana (edoxaban) promotional meeting titled: 'Anticoagulation in stroke prevention: Optimising clinical and medicines management' (EDX/21/0047) (March 2021) was organised and funded by Daiichi-Sankyo UK. Health board members, pharmacy assistants and education providers were invited to this meeting. The complainant alleged that this was inappropriate as these three particular groups should not have been promoted to. A headline claim that Anticoagulation with DOACs was cost effective was alleged to be misleading as no cost-effective analysis had been done for Lixiana. There was only the acquisition cost for Lixiana which could not be expanded to cost effectiveness. The complainant stated that, more concerning however, was that this promotional video had been placed onto Vimeo after the event. Vimeo was an open access website and was not limited to professional use and therefore members of the public had allegedly been promoted to. The complainant further alleged that Daiichi-Sankyo had breached an undertaking in promotion to members of the public from a previous case (Case AUTH/3107/10/18).

Case AUTH/3513/5/21

The complainant stated that a promotional video titled: 'Anticoagulation in stroke prevention: optimising clinical and medicines management' had been uploaded onto Vimeo and discussed Lixiana (edoxaban). The complainant alleged that a prescription only medicine (Lixiana) had been promoted to members of the public. This was alleged to be a breach of an undertaking Daiichi-Sankyo had provided in a previous case (Case AUTH/3107/10/18). The video was uploaded onto Vimeo by someone working for a third party on behalf of Daiichi-Sankyo. This was a breach of the Code including Clause 2 as pharmaceutical companies were responsible for acts of third parties. Health board members, education providers and practice managers had been invited to this promotional session. None of these were prescribers so the content was allegedly not

appropriate or tailored for these three audiences. The complainant stated it was very disappointing that Daiichi-Sankyo were not adhering to the Code.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that it was approached by the organisers of the Celtic Conference 2020 for sponsorship of a lunchtime symposium; Daiichi-Sankyo was not involved in the organisation or content of the entire conference.

The Panel noted that the conference agenda stated 'This event will be funded by the following companies through event sponsorship and sponsored sessions. These companies have had no input into the design or content of the workshop agenda (other than their own sessions) but will be in attendance on the day' and listed Daiichi-Sankyo as a silver sponsor. Further, it stated 'This promotional symposium is organised and sponsored by Daiichi-Sankyo UK Ltd' in relation to the session titled 'Anticoagulation in stroke prevention: Optimising clinical and medicines management'.

The Panel noted the complainant's concern that it was inappropriate for health board members, pharmacy assistants and education providers to be invited to Daiichi-Sankyo's session as promotion should be tailored to those who it was appropriate for, and these three particular groups should not have been promoted to.

The Panel noted Daiichi-Sankyo's submission that its session in question was advertised through the conference agenda by the meeting organisers who sent a flyer to the organiser's database of verified health professionals. Due to General Data Protection Regulation (GDPR), the meeting organisers were unable to share their database with Daiichi-Sankyo but confirmed that they were verified health professionals.

The Panel noted that the invitation to the Daiichi-Sankyo session stated 'This promotional symposium is for UK healthcare professionals only and has been organised and sponsored by Daiichi-Sankyo UK Ltd. [Click here for prescribing information](#)'. The Panel further noted Daiichi-Sankyo's submission that only delegates who had registered for the event via the meeting organisers website received a dial-in link for the event, and before they were sent this link it was once again confirmed that they were health professionals. The Panel noted Daiichi-Sankyo's submission that health board members and education providers were collective terms for health professionals who might occupy a variety of relevant roles. Daiichi-Sankyo provided a copy of the attendee list and submitted that only health professionals and other relevant decision makers were in attendance. Daiichi-Sankyo submitted that no pharmacy assistants were in attendance, but pharmacy technicians were as they were relevant health professionals.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case, on the balance of probabilities, that any attendees at the Daiichi-Sankyo session were inappropriate as alleged. The Panel therefore ruled no breaches of the Code.

The Panel noted the complainant's allegation that the claim 'Anticoagulation with DOACs is cost effective' was misleading as no cost-effective analysis had been done for Lixiana. The Panel noted that the term 'cost-effective' meant more than just a comparison of the acquisition costs, both direct and indirect costs should

betaken into account such as resource. Other factors, such as relative efficacy and incidence of side effects, might also be relevant. The Panel noted Daiichi-Sankyo's submission that all four DOACs (including Lixiana) had NICE Health Technology Appraisals (HTAs) which confirmed their cost effectiveness. The NICE HTA for Lixiana was published on 23 September 2015 and included that '...edoxaban could be recommended as a cost-effective treatment for non-valvular atrial fibrillation in people who have 1 or more risk factors for stroke.'

The Panel noted that the NICE HTA had not been cited as a reference for the claim. The Panel noted that the complainant bore the burden of proof and considered that, on the evidence before it, the complainant had not established that there was no cost-effective analysis for Lixiana as alleged. Based on the very narrow allegation, the Panel thus ruled no breaches of the Code.

The Panel noted that the agreement with the meeting organisers stated that the materials provided by Daiichi-Sankyo for use at the conference must only be accessible to healthcare professionals and must not be replicated or adapted on any other platform whereby they would be accessible to members of the public. The Panel noted Daiichi-Sankyo's submission that meeting organisers placed a recording of the event on the platform Vimeo, in order to share the recording of the symposium with Daiichi-Sankyo only. The Panel noted Daiichi-Sankyo's submission that it understood that the video link was private and only accessible to Daiichi-Sankyo recipients. It appeared, however, that the video did not have the correct privacy settings in place on the Vimeo account due to an error of the meeting organisers and members of the public might have been able to access the video on Vimeo. The Panel noted Daiichi-Sankyo's submission that it asked for the video to be removed as soon as it was brought to its attention that it was available in the public domain and the meeting organisers confirmed the removal of the video from Vimeo.

The Panel noted Daiichi-Sankyo's submission that the meeting organisers were not a third-party agency acting on behalf of Daiichi-Sankyo. However, the Panel considered that, for the purposes of the sponsored symposia, Daiichi-Sankyo had in effect purchased advertising space from the meeting organisers and therefore Daiichi-Sankyo was thus responsible for the placement of the promotional video at issue on Vimeo by the meeting organisers. The Panel considered that the promotional video on Vimeo did not have the correct privacy settings in place due to an error of the meeting organisers and therefore was viewable by members of the public. The Panel therefore ruled breaches of the Code as Lixiana, a prescription only medicine, had been advertised to the public and the material might have encouraged an individual to ask his/her health professional to prescribe Lixiana.

The Panel noted Daiichi-Sankyo's submission that it took appropriate steps via contractual stipulations and a disclaimer on the slide to prevent members of the public from accessing or viewing the recording. It appeared to the Panel that Daiichi-Sankyo had been let down by the meeting organisers not assigning the correct privacy settings to the video in question.

The Panel did not consider that the particular circumstances of this case were such that Daiichi-Sankyo had failed to maintain high standards or had brought discredit upon the industry and thus ruled no breaches of the Code including no breach of Clause 2.

The Panel noted that in Case AUTH/3107/10/18, Daiichi-Sankyo was ruled in breach of the Code as a webpage on the corporate website advertised prescription only medicines to the public and access to that webpage had not been restricted to health professionals and other relevant decision makers and its undertaking, accepting the Panel's decision, was dated 22 February 2019. Turning to the present cases, Cases AUTH/3507/5/21 and AUTH/3513/5/21, the Panel noted that as a result of the meeting organisers, unbeknown to Daiichi-Sankyo, the video of its promotional session was added to Vimeo without the correct privacy settings which meant that it was possible to be viewed by a broader audience than intended including members of the public.

The Panel considered that Cases AUTH/3507/5/21 and AUTH/3513/5/21 were sufficiently different to Case AUTH/3107/10/18 such that there had been no breach of the undertaking given in that case. In particular, the Panel noted the role of the meeting organisers in Cases AUTH/3507/5/21 and AUTH/3513/5/21. Therefore, no breaches of the Code were ruled including no breach of Clause 2.

An anonymous complainant who was originally contactable but later became non-contactable complained about the promotion of Lixiana (edoxaban).

Lixiana (edoxaban) was indicated, *inter alia*, in prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age \geq 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).

The complainant submitted two separate complaints: Case AUTH/3507/5/21 and Case AUTH/3513/5/21. The Case Preparation Manager decided to amalgamate the two cases as they were based on essentially similar evidence, in accordance with Paragraph 5.1 of the Constitution and Procedure. The complainant did not appeal the Case Preparation Manager's decision to amalgamate the two cases.

Case AUTH/3507/5/21

COMPLAINT

The complainant stated that the Lixiana (edoxaban) promotional meeting titled: 'Anticoagulation in stroke prevention: Optimising clinical and medicines management' (EDX/21/0047) (March 2021) was organised and funded by Daiichi-Sankyo UK. Health board members, pharmacy assistants and education providers were invited to this meeting. The complainant alleged that this was inappropriate as promotion should be tailored to those who it was appropriate for and these three particular groups should not have been promoted to. This was a breach of Clauses 11.1 and 9.1. The complainant stated that at 34 minutes and 58 seconds into the presentation, a headline claim was made that Anticoagulation with DOACs was cost effective. This was in big bold font. However, this was allegedly misleading as no cost-effective analysis had been done for Lixiana. There was only the acquisition cost for Lixiana which could not be expanded to cost effectiveness. This was a breach of Clauses 7.2, 7.4 and 9.1. The complainant stated that, more concerning however, was that this promotional video had been placed onto Vimeo after the event. Vimeo was an open access website and was not limited to professional use and therefore members of the public had allegedly been promoted to. This was in breach of Clauses 26.1, 26.2, 9.1 and 2. The complainant further alleged that Daiichi-Sankyo had breached an undertaking in promotion to members of the public from a previous case (Case

AUTH/3107/10/18). Therefore, due to the video being on Vimeo, this was a breach of Clause 29, 9.1 and 2.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 29, 26.2, 26.1, 11.1, 9.1, 7.4, 7.2 and 2 of the Code.

Case AUTH/3513/5/21

COMPLAINT

The complainant stated that a promotional video titled: 'Anticoagulation in stroke prevention: optimising clinical and medicines management' (EDX/21/0047) (March 2021) had been uploaded onto Vimeo. Lixiana (edoxaban) was discussed in detail in this promotional video. The complainant provided the link to the video on Vimeo (<https://vimeo.com/524859423>) and explained that Vimeo was an open access platform accessible by the general public and therefore alleged that a prescription only medicine (Lixiana) had been promoted to members of the public. The complainant stated that this was in breach of Clauses 26.1, 26.2, 9.1 and 2. Not promoting to members of the public was also an undertaking Daiichi-Sankyo had provided in a previous case (Case AUTH/3107/10/18 – Complainant v Daiichi-Sankyo. Alleged promotion to the public). Therefore, Daiichi-Sankyo had allegedly breached an undertaking with this promotional Vimeo video which was a breach of Clause 29 and Clause 2. The user who had uploaded the video onto Vimeo was a third party personnel working on behalf of Daiichi-Sankyo. This was a breach of Clause 9.1 and Clause 2 as pharmaceutical companies were responsible for acts of third parties. As could be seen on the video at 3 minutes and 4 seconds, health board members, education providers and practice managers had been invited to this promotional session. None of these were prescribers so the content was allegedly not appropriate or tailored for these three audiences. This was a breach of Clause 11.1. The complainant stated it was very disappointing that Daiichi-Sankyo were not adhering to the Code despite audits and a new medical director in place. One would have to question whether a compliance culture existed at the company.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 29, 26.2, 26.1, 11.1, 9.1 and 2 of the Code.

RESPONSE

Daiichi-Sankyo provided a joint response to Cases AUTH/3507/5/21 and AUTH/3513/5/21.

Daiichi-Sankyo stated that it fully appreciated the decision to amalgamate both cases, given that the allegations were from the same complainant based on closely similar evidence. Daiichi-Sankyo UK stated that it took its obligations under the Code seriously and strove to maintain high standards and behave responsibly and ethically at all times. Daiichi-Sankyo stated that the complainant alleged breaches of Clauses 29, 26.2, 26.1, 11.1, 9.1, 7.4, 7.2 and 2 of the Code. In addition, Daiichi-Sankyo was asked specifically to respond to Clause 2 in relation to the alleged breach of undertaking.

Daiichi-Sankyo denied all breaches.

Background Information and response to individual breach allegations

Daiichi-Sankyo submitted that all of the allegations were related to Job Code EDX/21/0047.
Date of preparation: March 2021.

This was a slide deck that was originally developed by Daiichi-Sankyo for an in-person event in March 2020. The organisers of this event approached Daiichi-Sankyo for sponsorship of a lunchtime symposium at the Celtic Conference 2020. Daiichi-Sankyo stated that it was not involved in the organisation or content of the event itself. Due to the COVID-19 pandemic, this in-person event was cancelled and subsequently run as a virtual meeting on 11 March 2021. As might be seen in the full day agenda (copy provided), a number of companies supported this event through sponsored sessions or symposia, but no company had input into the design or content of the workshop agenda (other than their individual sessions).

Daiichi-Sankyo submitted that the meeting organisers were not a third-party agency working on behalf of Daiichi-Sankyo UK.

The meeting in question was advertised through the entire conference agenda by the meeting organisers, who sent a flyer to its database of verified health professionals in line with the information on the Celtic Conference website. Due to General Data Protection Regulation (GDPR), the meeting organiser was unable to share its database but confirmed that they were verified health professionals.

Aside from other sponsoring companies, only delegates who had registered for the event via the meeting organisers website received a dial-in link for the event, and before they were sent this link it was once again confirmed that they were health professionals by the meeting organisers.

Daiichi-Sankyo provided a copy of the attendee list. As could be seen, only health professionals and other relevant decision makers were in attendance. Health board members and education providers were collective terms for health professionals who might occupy a variety of relevant roles. There were no pharmacy assistants in attendance. Pharmacy technicians did attend as they were relevant health professionals, as stated on the NHS Health Careers website (Pharmacy technician | Health Careers) and the General Pharmaceutical Council (Pharmacy technician education and training | General Pharmaceutical Council (pharmacyregulation.org)). Daiichi-Sankyo provided a copy of the Celtic Conference homepage with the intended health professional audience.

As demonstrated above, only health professionals were invited to the Daiichi-Sankyo symposium, therefore Daiichi-Sankyo denied a breach of Clause 11.1.

There was no evidence that high standards had not been maintained, therefore Daiichi-Sankyo denied a breach of Clause 9.1.

Regarding the headline claim that Anticoagulation with DOACs was cost effective, Daiichi-Sankyo submitted that all four DOACs (including Lixiana) had NICE Health Technology Appraisals (HTAs) which confirmed their cost effectiveness. The NICE HTA for Lixiana was published on 23 September 2015 and stated:

‘The Committee concluded that there was insufficient evidence to distinguish between the clinical and cost effectiveness of edoxaban and the newer oral anticoagulants recommended in previous appraisals (apixaban, dabigatran etexilate and rivaroxaban).

Therefore, edoxaban could be recommended as a cost-effective treatment for non-valvular atrial fibrillation in people who have 1 or more risk factors for stroke.'

A copy of the marked up NICE HTA was provided.

Daiichi-Sankyo stated that the acquisition cost for Lixiana was only provided as an immediate visual comparison to illustrate the cost of patient treatment for 1 year, versus the cost of stroke. Not as a demonstration of cost effectiveness. Therefore, this was not a misleading claim as NICE considered edoxaban to be a cost-effective treatment in line with previous DOAC HTAs.

Therefore, Daiichi-Sankyo denied providing misleading information and denied a breach of Clause 7.2.

Daiichi-Sankyo stated that it was able to substantiate that Lixiana was a cost effective DOAC and denied a breach of Clause 7.4.

There was no evidence that high standards had not been maintained, therefore Daiichi-Sankyo denied a breach of Clause 9.1.

Daiichi-Sankyo denied promoting to members of the public. The third party sponsorship contract signed by the meeting organisers in February 2021, clearly stated:

'These materials must only be accessible to Healthcare Professionals and all materials need prior approval from Daiichi Sankyo. This must not be replicated or adapted on any other platform whereby this would be accessible to members of the public and no wording or approved content should be altered.'

The meeting organisers placed a recording of the event on the platform Vimeo, in order to share the recording of the symposium with Daiichi-Sankyo only.

Daiichi-Sankyo provided a response from the meeting organisers, stating:

'Firstly, we would like to take the opportunity to apologise for the fact that this video did not have the correct privacy settings in place on the Vimeo account. This *does* not meet with our SOP or usual high standards and we are dealing with that internally.

We have also spoken with our internal compliance team with regards to this issue and gathered the following information which we felt may be of value to you. The below points were based on the assumption that the complaint appears to be that Daiichi-Sankyo (DS) has promoted a prescription-only medicine to the public:

- A link to the recording of a promotional meeting was emailed from [the meeting organisers] to [Daiichi-Sankyo]. The recording was held on Vimeo and the link was specific to that recording. The email was sent only to a specific recipient at [Daiichi-Sankyo]. The recording has not been made public or sent by [the meeting organisers] to any meeting attendees.
- Any user who has previously received Vimeo links from [the meeting organisers] e.g. attendees at previous meetings organised by [the meeting organisers], could also potentially access other videos in this way. However, all attendees are

health professionals; no members of the public are eligible to attend meetings organised by [the meeting organisers]. Hence, no Vimeo links would be sent to members of the public by [the meeting organisers].'

As soon as it was brought to the attention of Daiichi-Sankyo that this video was available in the public domain, Daiichi-Sankyo immediately asked for it to be removed. The email response from the meeting organisers - was provided which confirmed removal of the video. Unfortunately, the meeting organisers could not confirm view numbers and believed only the people at its organisation and Daiichi-Sankyo employees had viewed the video. A number of Daiichi-Sankyo employees viewed the video as part of the investigation into the alleged complaint.

As the video had been completely removed from the Vimeo site, Daiichi-Sankyo was not able to produce screenshots showing the amount of views the video had. There would be no way of confirming who viewed the video.

Daiichi-Sankyo understood that the video link was private and only accessible to Daiichi-Sankyo recipients. Daiichi-Sankyo took appropriate steps via contractual stipulations, and disclaimer on the slide to prevent members of the public from accessing or viewing the recording. Daiichi-Sankyo was not aware that this video could be viewed by members of the public and was disappointed that due to an error of the meeting organisers, members of the public were able to access the video on Vimeo. However, the third-party meeting organiser was not acting on behalf of Daiichi-Sankyo UK.

Therefore, Daiichi-Sankyo denied a breach of Clause 26.1.

As there was no intention by Daiichi-Sankyo to promote to the public and it took appropriate steps to prevent members of the public from viewing the recording, Daiichi-Sankyo denied a breach of Clause 26.2.

Daiichi-Sankyo submitted that there was no evidence that high standards had not been maintained, therefore Daiichi-Sankyo denied a breach of Clause 9.1.

Daiichi-Sankyo submitted that it took all reasonable and necessary steps to prevent members of the public from viewing any recording through the agreement and the disclaimer on the first slide, and the recording was intended for health professionals only, therefore Daiichi-Sankyo denied breach of Clause 2.

Daiichi-Sankyo submitted that following the ruling in Case AUTH/3107/10/18, Daiichi-Sankyo had implemented the following steps and processes:

Content on the Daiichi-Sankyo UK website:

- a) Removed the product content that was subject to the original complaint.
- b) Updated the product content to contain product name, SPC and PIL.
- c) Reviewed and certified <https://www.daiichi-sankyo.co.uk/> website content on a regular and frequent basis to ensure there was no promotional content.
- d) Created clear policies and protocols for corporate website management, including clear lines of accountability and ownership amongst Daiichi-Sankyo UK employees.

- e) Ensured all relevant staff and teams responsible for non-promotional external communications and website content undertake regular internal and externally provisioned training on the Code.

Contrary to the argument put forward by the complainant, Daiichi-Sankyo UK denied a breach of undertaking. Daiichi-Sankyo UK submitted that it took the breach of an undertaking very seriously: and took all the necessary steps to ensure that the material in question with regards to Case AUTH/3107/10/18 was discontinued, removed and no longer in use and applied the learnings for future activities.

Daiichi-Sankyo stated that it had taken all steps to ensure compliance with the undertaking given in Case AUTH/3107/10/18 and therefore denied breaches of Clauses 29, 9.1 and 2.

Case AUTH/3513/5/21

Daiichi-Sankyo stated that given that the two cases were from the same complainant and based on similar allegations, the company had decided to address the aspect above which was different to the allegations in Case AUTH/3507/5/21. The Panel was asked to refer to Daiichi-Sankyo's above response in relation to the allegations regarding the breach of Clauses 29, 26.2, 26.1, 11.1, 9.1 and 2 as referred to by the complainant and in relation to the alleged breach of undertaking.

Daiichi-Sankyo denied breaches of Clauses 9.1 and 2.

Daiichi-Sankyo submitted that the individual who uploaded the video on Vimeo was employed by the meeting organisers which was not a third party agency working on behalf of Daiichi-Sankyo, as the Celtic Conference was a meeting organised and run by them. Daiichi-Sankyo sponsored this third-party independent conference and was only involved in the content presented at the lunchtime company symposium but had no input into the programme design or content of the day or any other workshop agendas. Therefore, Daiichi-Sankyo denied breaches of Clauses 9.1 and 2.

Conclusion

Daiichi-Sankyo stated that it trusted that the Panel would see that, based on the evidence provided above, Daiichi-Sankyo UK had acted in line with the requirements of the Code, maintained high standards and had not brought discredit upon, or reduced confidence in, the industry.

PANEL RULING

The Panel noted that the Constitution and Procedure stated that 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 Daiichi-Sankyo's submission that it was approached by the organisers of the Celtic Conference 2020 for sponsorship of a lunchtime symposium; Daiichi-Sankyo was not involved in the organisation or content of the entire conference.

The Panel noted that the conference agenda stated 'This event will be funded by the following companies through event sponsorship and sponsored sessions. These companies have had no input into the design or content of the workshop agenda (other than their own sessions) but will be in attendance on the day' and listed Daiichi-Sankyo as a silver sponsor. Further, it stated 'This promotional symposium is organised and sponsored by Daiichi-Sankyo UK Ltd' in relation to the session titled 'Anticoagulation in stroke prevention: Optimising clinical and medicines management'.

The Panel noted the complainant's concern that it was inappropriate for health board members, pharmacy assistants and education providers to be invited to Daiichi-Sankyo's session as promotion should be tailored to those who it was appropriate for, and these three particular groups should not have been promoted to.

The Panel noted Daiichi-Sankyo's submission that its session in question was advertised through the conference agenda by the meeting organisers, who sent a flyer to the organiser's database of verified health professionals. Due to General Data Protection Regulation (GDPR), the organisers were unable to share their database with Daiichi-Sankyo but confirmed that they were verified health professionals.

The Panel noted that the invitation to the Daiichi-Sankyo session stated 'This promotional symposium is for UK healthcare professionals only and has been organised and sponsored by Daiichi-Sankyo UK Ltd. [Click here for prescribing information](#)'. The Panel further noted Daiichi-Sankyo's submission that only delegates who had registered for the event via the meeting organiser's website received a dial-in link for the event, and before they were sent this link it was once again confirmed that they were health professionals. The Panel noted Daiichi-Sankyo's submission that health board members and education providers were collective terms for health professionals who might occupy a variety of relevant roles. Daiichi-Sankyo provided a copy of the attendee list and submitted that only health professionals and other relevant decision makers were in attendance. Daiichi-Sankyo submitted that no pharmacy assistants were in attendance, but pharmacy technicians were as they were relevant health professionals.

Clause 11.1 stated that material should only be sent or distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed. The supplementary information stated that material should be tailored to the audience to whom it was directed. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case, on the balance of probabilities, that any attendees at the Daiichi-Sankyo session were inappropriate as alleged. The Panel therefore ruled no breach of Clause 11.1 and consequently no breach of Clause 9.1.

The Panel noted the complainant's allegation that the claim 'Anticoagulation with DOACs is cost effective' was misleading as no cost-effective analysis had been done for Lixiana. The Panel noted that the term 'cost-effective' meant more than just a comparison of the acquisition costs, both direct and indirect costs should be taken into account such as resource. Other factors, such as relative efficacy and incidence of side effects, might also be relevant. The Panel noted Daiichi-Sankyo's submission that all four DOACs (including Lixiana) had NICE Health Technology Appraisals (HTAs) which confirmed their cost effectiveness. The NICE HTA for Lixiana was published on 23 September 2015 and stated:

'The Committee concluded that there was insufficient evidence to distinguish between the clinical and cost effectiveness of edoxaban and the newer oral anticoagulants

recommended in previous appraisals (apixaban, dabigatran etexilate and rivaroxaban). Therefore, edoxaban could be recommended as a cost-effective treatment for non-valvular atrial fibrillation in people who have 1 or more risk factors for stroke.'

The Panel noted that the NICE HTA had not been cited as a reference for the claim. The Panel noted that the complainant bore the burden of proof and considered that, on the evidence before it, the complainant had not established that there was no cost-effective analysis for Lixiana as alleged. Based on the very narrow allegation, the Panel thus ruled no breach of Clauses 7.2 and 7.4 and consequently no breach of Clause 9.1.

The Panel noted that the agreement with the meeting organisers stated that the materials provided by Daiichi-Sankyo for use at the conference must only be accessible to healthcare professionals and must not be replicated or adapted on any other platform whereby they would be accessible to members of the public. The Panel noted Daiichi-Sankyo's submission that the meeting organisers placed a recording of the event on the platform Vimeo, in order to share the recording of the symposium with Daiichi-Sankyo only. The Panel noted Daiichi-Sankyo's submission that it understood that the video link was private and only accessible to Daiichi-Sankyo recipients. It appeared, however, that the video did not have the correct privacy settings in place on the Vimeo account due to an error of the meeting organisers and members of the public might have been able to access the video on Vimeo. The Panel noted Daiichi-Sankyo's submission that it asked for the video to be removed as soon as it was brought to its attention that it was available in the public domain and the meeting organisers confirmed the removal of the video from Vimeo.

The Panel noted that it was a well-established principle that a company was responsible for the acts or omissions of its agents or third parties. If this were not the case, companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. The Panel noted Daiichi-Sankyo's submission that the meeting organisers were not a third-party agency acting on behalf of Daiichi-Sankyo. However, the Panel considered that, for the purposes of the sponsored symposia, Daiichi-Sankyo had in effect purchased advertising space from the meeting organisers and therefore Daiichi-Sankyo was thus responsible for the placement of the promotional video at issue on Vimeo by the meeting organisers. The Panel noted Daiichi-Sankyo's submission that the meeting organisers believed that the only individuals who had viewed the video on Vimeo before it was deleted were the meeting organisers and Daiichi-Sankyo employees. The Panel, however, considered that the promotional video on Vimeo did not have the correct privacy settings in place due to an error of the meeting organisers and therefore was viewable by members of the public. The Panel therefore ruled a breach of Clauses 26.1 and 26.2 as Lixiana, a prescription only medicine, had been advertised to the public and the material might have encouraged an individual to ask his/her health professional to prescribe Lixiana.

The Panel noted Daiichi-Sankyo's submission that it took appropriate steps via contractual stipulations and a disclaimer on the slide to prevent members of the public from accessing or viewing the recording. It appeared to the Panel that Daiichi-Sankyo had been let down by the meeting organisers not assigning the correct privacy settings to the video in question. The Panel did not consider that the particular circumstances of this case were such that Daiichi-Sankyo had failed to maintain high standards or had brought discredit upon the industry and thus ruled no breach of Clauses 9.1 and 2.

The Panel noted that in Case AUTH/3107/10/18, Daiichi-Sankyo was ruled in breach of the Code as a webpage on the corporate website advertised prescription only medicines to the public and access to that webpage had not been restricted to health professionals and other relevant decision makers and its undertaking, accepting the Panel's decision, was dated 22 February 2019. Turning to the present cases, Cases AUTH/3507/5/21 and AUTH/3513/5/21, the Panel noted that as a result of the meeting organisers, unbeknown to Daiichi-Sankyo, the video of its promotional session was added to Vimeo without the correct privacy settings which meant that it was possible to be viewed by a broader audience than intended including members of the public.

The Panel considered that Cases AUTH/3507/5/21 and AUTH/3513/5/21 were sufficiently different to Case AUTH/3107/10/18 such that there had been no breach of the undertaking given in that case. In particular, the Panel noted the role of the meeting organisers in Cases AUTH/3507/5/21 and AUTH/3513/5/21. Therefore, no breach of Clause 29 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2.

Complaint received 3 May 2021

Case completed 6 December 2021