

CASE AUTH/3417/11/20

COMPLAINANT v DAIICHI-SANKYO

Alleged promotion of Lixiana on YouTube

An anonymous, contactable patient complained about the promotion of Lixiana (edoxaban) on YouTube by Daiichi-Sankyo UK. Lixiana was an anticoagulant indicated for the prevention and treatment of certain thrombotic events.

The complainant explained that he/she took an anticoagulant and found the YouTube video sponsored by Daiichi-Sankyo UK on a page run by a medical education company. The video was a recording of a meeting that happened on 8 July 2020.

The complainant noted that there was a company logo at the beginning of the video but no other explanation of the company involvement and the speaker did not mention that the video was sponsored by the company until five minutes had lapsed. The complainant stated that he/she did not think it was true that the company had had no input; there were four slides which must have been produced by the company and they promoted its medicine. The complainant queried how the third party medical education company received these slides if the company had not provided them and asked for them to be inserted in return for sponsorship. Breaches of the Code were alleged including that the slides were disguised promotion.

The complainant alleged that the video promoted edoxaban to the public because YouTube was a public site and there was nowhere in the video or on the YouTube page that said only health professionals should watch the video. Breaches of the Code were alleged.

The complainant stated that if it was promotion, the company should provide some information such as prescribing information and details to report adverse events and but there should have been a black triangle where edoxaban was mentioned on the slides. Breaches of the Code were alleged.

Given all of the above, the complainant queried whether the company had even scrutinised and approved or 'certified' the video and in that regard he/she alleged breaches of the Code.

The complainant stated that this led to a further question of whether the speakers were under a contract with Daiichi-Sankyo given that this was a promotional meeting with slides provided by the company, but the speaker stated the company had no involvement in the content. The complainant alleged a breach of the Code if there were no proper contracts instructing the speaker to accurately describe the company's involvement.

The complainant alleged that the company had not maintained high standards and that this kind of underhand activity, to falsely claim no involvement in the content of a meeting, reduced confidence in the pharmaceutical industry in breach of Clause 2.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that the YouTube video in question was of the medical education company-organised main clinical session from a meeting initiated and coordinated by the medical education company held on 8 July 2020. Daiichi-Sankyo had provided sponsorship for the meeting and in return was able to provide speakers for some parts of the agenda.

The Panel noted Daiichi-Sankyo's submission that the agenda was split into a formal clinical session and several Daiichi-Sankyo sponsored sessions; the medical education company had selected half of the speakers and Daiichi-Sankyo had selected the other half. Daiichi-Sankyo stated that it had full control in selecting, briefing and contracting the speakers for its sponsored sessions. Daiichi-Sankyo did not have any involvement in identifying attendees for the event.

The Panel made its ruling on the basis of the five screenshots provided by the complainant.

The Panel noted Daiichi-Sankyo's submission that neither it nor the medical education company had uploaded the presentation onto YouTube for public viewing. According to Daiichi-Sankyo the medical education company routinely made the recordings available via a portal and delegate dashboard linked to the non-public YouTube infrastructure to those delegates. The medical education company used an unlisted YouTube channel to store the recording so that it could edit it and provide a version to the delegates. The Panel noted Daiichi-Sankyo's submission that the recordings could not be accessed by the public, or anyone else, unless they had the direct link and that the only people with access to the link provided by the complainant were the delegates attending the event who were all confirmed as health professionals. If the link was entered into a Google web browser that search would nonetheless identify the video in question.

It appeared to the Panel that the video in question could only be accessed via a specific link which had only been made available to delegates. On the limited information before the Panel, it appeared unlikely, on the balance of probabilities, that the video would be accessed by searching YouTube or the wider internet. The Panel also bore in mind Daiichi-Sankyo's submission that the screenshots of the video in question provided by the complainant appeared to have been accessed by the link provided to delegates. The Panel considered that the complainant had not established, on the balance of probabilities, that the publication of the video in question on YouTube meant that it was available to the public as alleged. In any event, it appeared that Daiichi-Sankyo had no role whatsoever in relation to the publication of the video in question. No breaches of the Code were ruled.

The Panel noted Daiichi-Sankyo's submission that the target audience of the meeting was pharmacists, and the content of the recording was appropriate for that audience. Noting its comments above about the publication of the video the Panel did not consider that the complainant had provided evidence that the recording had been sent or

distributed by Daiichi-Sankyo to anyone whose need for or interest in it could not be reasonably assumed and no breach of the Code was ruled.

The Panel noted Daiichi-Sankyo's submission that whilst it certified the presentations in its company sessions, it did not initiate or influence the content of the presentation in the video in question, did not choose the speaker and therefore did not review the slides. The Panel noted that the speaker in the video in question had access to Daiichi-Sankyo slides from a different project and had, without the company's permission, used some of those slides in the presentation in question which was not under Daiichi-Sankyo's control. The Panel noted Daiichi-Sankyo's submission that it had included the appropriate mandatory information in its presentations, however, the material shown in the video in question was not promotional content created by or for Daiichi-Sankyo. The Panel considered, on the evidence before it, that Daiichi-Sankyo was not responsible for the content of the presentation in question in relation to the clauses cited and, in that regard, ruled no breaches of the Code.

The Panel noted Daiichi-Sankyo's submission that it did not choose the speaker or initiate or influence the content of the presentation shown in the recording. Nor had the company paid the speaker in question in relation to his/her presentation. The Panel therefore ruled no breach of the Code.

The Panel considered that Daiichi-Sankyo had been badly let down by the speaker of the presentation in question who had been a consultant of Daiichi-Sankyo's in a previous project and had re-purposed Daiichi-Sankyo material in his/her presentation without the company's permission and this had contributed to the misleading impression that Daiichi-Sankyo was involved with the content of that particular session which was not so. Furthermore, the medical education company appeared not to have followed its own policies as it did not review the slides from the presentation in question and the moderator did not intervene to prevent any 'un-reviewed' slides from being displayed. It was a well-established principle that companies were responsible under the Code for the acts and omissions of its consultants and third parties working on its behalf. However, the Panel noted, that in this particular case, the speaker in question was not acting as a consultant to the company and the medical education company was not working on Daiichi-Sankyo's behalf. Daiichi-Sankyo had provided sponsorship to the medical education company for the entire meeting and in return Daiichi-Sankyo was able to provide speakers for some sessions on the agenda. Those sessions were labelled as optional and signposted on the agenda as 'Sponsored by Daiichi-Sankyo'. The Panel noted that according to Daiichi-Sankyo delegates had to visit a separate virtual room to access these sessions and in the Panel's view, Daiichi-Sankyo was responsible under the Code for the content of these sessions. The Panel considered, however, that in the particular circumstances of this case Daiichi-Sankyo was not responsible for the content of the independent sessions that it had no influence on, which included the session in the YouTube video in question. The Panel noted its comments above and considered that there was no evidence to show that Daiichi-Sankyo had failed to maintain high standards in that regard and no breach of the Code was ruled.

The Panel noted that the Code stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. The supplementary information stated that the declaration

of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. The Code stated that when meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

The Panel noted that Daiichi-Sankyo's logo appeared on two slides of the presentation at issue provided by the complainant; the first slide and the slide displaying the agenda for the whole meeting. Further, four of the slides discussing edoxaban were Daiichi-Sankyo branded slides. Whilst noting Daiichi-Sankyo's submission that the speaker re-purposed material from a different Daiichi-Sankyo project without the company's permission and that the Daiichi-Sankyo sessions at the virtual meeting in question were signposted as such, it did not consider that Daiichi-Sankyo's sponsorship of the meeting overall and its lack of involvement in the particular session was sufficiently clear from the outset of the presentation. A company logo was considered insufficient in this regard and a verbal briefing about sponsorship did not negate the need for a written unambiguous declaration of sponsorship. Further, the Panel did not know what was said in the verbal briefing. Breaches of the Code were ruled. High standards had not been maintained in that regard and a breach of the Code was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of this clause and therefore no breach of Clause 2 was ruled which was upheld on appeal by the complainant.

An anonymous, contactable patient complained about the promotion of Lixiana (edoxaban) on YouTube by Daiichi-Sankyo UK Limited. Lixiana was an anticoagulant indicated for the prevention and treatment of certain thrombotic events.

COMPLAINT

The complainant explained that he/she took an anticoagulant and found the YouTube video (link provided) on a page run by a medical education company; the video was sponsored by Daiichi-Sankyo UK Ltd. The complainant alleged that the video promoted edoxaban which he/she thought was not allowed on a public website like YouTube.

The complainant stated that there was nothing on the YouTube page to denote that the video was only to be seen by health professionals. There was nothing to stop a member of the public like him/her from watching the video. The video was a recording of a meeting that happened on 8 July 2020.

The complainant provided some pictures from the video.

The complainant stated that the first picture at time 0:00 showed the Daiichi-Sankyo logo, but there was nothing to explain how Daiichi-Sankyo was involved.

The complainant stated that at 5:00 the speaker stated Daiichi-Sankyo was the sponsor but had no input into the educational content. This was the first time the involvement of the company was mentioned by the speaker. The complainant stated that he/she did not think it was true that the company had had no input as explained below. It also looked from the agenda shown at this time point that there were other optional sessions sponsored by Daiichi-Sankyo but they were not on the video. The complainant stated that his/her complaint only related to the main sessions which were in the video.

At 1:09:21 there was a slide that had very obviously been produced by the company, it had the Daiichi-Sankyo logo and had information which compared edoxaban with another anticoagulant, warfarin. At 1:22:38, 1:23:32 and 1:30:14 there were more company slides which compared edoxaban and warfarin.

The complainant stated that he/she thought it was not true when the speaker said the company had had no input into the educational content. There were four slides which must have been produced by the company and they promoted its medicine. The complainant queried how the medical education company received these slides if the company had not provided them and asked for them to be inserted into the meeting in return for sponsorship.

The complainant stated that he/she thought it must be promotion to the public because YouTube was a public site and there was nowhere in the video or on the YouTube page that said only health professionals should watch the video. The complainant alleged breaches of Clauses 11.1, 26.1 and 28.1.

The complainant noted that there was a company logo at the beginning of the video but no other explanation of the company involvement and the speaker did not mention that the video was sponsored by the company until five minutes had lapsed. In that regard, the complainant alleged breaches of Clauses 9.10 and 22.4.

The complainant considered that if, as stated by the speaker, the company had had no input, but then Daiichi-Sankyo had provided slides promoting its medicine, that must mean it was disguised promotion. The complainant alleged a breach of Clause 12.1.

The complainant stated that if it was promotion, the company should provide some information such as prescribing information and details to report adverse events but he/she had watched the whole video and those details were not there. The complainant also noted that there should have been a black triangle where edoxaban was mentioned on the slides because edoxaban was under increased safety monitoring, but he/she did not see a black triangle on the slides. The complainant alleged breaches of Clause 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 and 4.10.

Given all of the above, the complainant queried whether the company had even scrutinised and approved or 'certified' the video and in that regard he/she alleged breaches of Clauses 14.1, 14.5 and 14.6.

The complainant stated that this led to a further question of whether the speakers were under a contract with Daiichi-Sankyo given that this was a promotional meeting with slides provided by the company, but the speaker stated the company had no involvement in the content. The complainant alleged a breach of Clause 23.1 if there were no proper contracts instructing the speaker to accurately describe the company's involvement.

The complainant stated that he/she did not believe the company had maintained high standards in breach of Clause 9.1.

The complainant alleged that this kind of underhand activity, to falsely claim no involvement in the content of a meeting, reduced confidence in the pharmaceutical industry in breach of Clause 2.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of the clauses cited by the complainant.

RESPONSE

Background

Daiichi-Sankyo stated that the complaint was based on a video hosted on YouTube and the fact it named a Daiichi-Sankyo product, edoxaban, and was visible to the public. Daiichi-Sankyo stated that the video was never visible to the general public. Nor did Daiichi-Sankyo have any role to play in the content of the video.

Daiichi-Sankyo explained that the video was a recording of a talk given by a named consultant pharmacist, at a meeting initiated and coordinated by a medical education company. Daiichi-Sankyo provided sponsorship to enable the online medical education event to take place. In return for sponsorship, Daiichi-Sankyo was able to provide speakers for some parts of the agenda, details were provided.

Daiichi-Sankyo stated that it did not initiate or influence the content of the presentation shown in the recording, did not choose the consultant pharmacist as a speaker and did not review the slides presented by him/her. Daiichi-Sankyo ensured that the sponsored sessions were appropriately labelled as such.

Daiichi-Sankyo stated that, essentially, the medical education company selected half the speakers and it selected the other half. The Daiichi-Sankyo sessions were clearly signposted to delegates as being sponsored (copy of the agenda was provided). For the sponsored sessions, Daiichi-Sankyo had full control in selecting, briefing and contracting the speakers. Daiichi-Sankyo approved the speaker's slides for its sponsored session, and did not have any involvement in identifying attendees, for the event.

Daiichi-Sankyo stated that the medical education company had been fully supportive of the company's investigations and ran its events to high standards in a Code-aware manner. On receipt of the complaint, the medical education company immediately worked with Daiichi-Sankyo to ascertain what had happened and immediately double-checked that no Daiichi-Sankyo sponsored sessions had been made live or publicly visible in any way.

Event

Daiichi-Sankyo submitted that the event in question was on 8 July, run by the medical education company with sponsorship and provision of some speakers from Daiichi-Sankyo. The webinar focussed on anticoagulation in complex patients. The delegates were all pharmacists.

The medical education company organised the invitations and controlled delegate attendance in several ways as part of its long-running approach to organising medical education. To attend an event, delegates had to register and provide their details – name, where they worked, GPHC number, mobile, email – and confirm they were health professionals. In addition, the GPHC numbers were checked.

For the type of webinar the medical education company ran in July, there was no on-demand joining; only pre-registered delegates would receive the link to the live webinar and a ‘waiting room’ was used as a screening device to ensure that only registered delegates were permitted to join the live event. Within the event, confidentiality was not permitted; all delegates had to display their first and last names or their access was blocked and they could not return. The process was more rigid than an in-person event.

Daiichi-Sankyo reiterated that the agenda was clearly split into a formal clinical session and several sponsored sessions. To access the sponsored sessions, the delegates had to enter a separate meeting room on a different portal (Zoom), so it was always obvious when the delegate was in an independent medical education company section of the event; and when they were in the Daiichi-Sankyo sponsored session.

The YouTube video showing Edoxaban

Daiichi-Sankyo noted that the recording highlighted by the complainant was of the medical education company organised main clinical session on the agenda ie the presentation made by a named consultant pharmacist. Daiichi-Sankyo further noted that none of its speakers appeared in the video.

Daiichi-Sankyo submitted that all the presentations made by its speakers were certified and it could provide, on request, evidence of the certification and copies of the slides.

Daiichi-Sankyo explained that the named consultant pharmacist had spoken for the medical education company several times previously on a similar topic; his/her medical education company slide deck was usually around 50-60 slides but at the event in question, there were 96 slides, which had not been previously submitted to the medical education company for review. The medical education company process was usually that its moderator would intervene to prevent any ‘un-reviewed’ slides being displayed. However, on this occasion, the medical education company process appeared not to have run smoothly.

The medical education company had confirmed to Daiichi-Sankyo that its standard policy was that none of the slides or content used by its speakers were allowed to be promotional (in the medical education sense). All the medical education company speaker presentations were developed by the speakers themselves and checked by the medical education company’s clinical team to ensure national guidelines were reflected in the presentation and there was no industry content or bias. The medical education company usually received copies of slides in advance of the event. The medical education company speakers were briefed to understand not only the audience but the importance of a presentation not being influenced by the sponsor.

The medical education company routinely recorded the presentations made by its speakers and made the recordings available via a portal and delegate dashboard to those delegates. This dashboard was linked to the non-public YouTube infrastructure (see explanation below).

Under normal circumstances the medical education company did not record the sponsored speaker sessions. However, the contractual arrangement with Daiichi-Sankyo showed that the medical education company had sought permission to record Daiichi-Sankyo's sponsored sessions. This appeared to be for contingency purposes rather than as an intent to distribute (eg forgetting to turn off the recording function at the appropriate time). The medical education company had therefore offered a recording of the Daiichi-Sankyo speakers as well, which was available on request.

Daiichi-Sankyo stated that usually, the only reference in the webinar event regarding the sponsor was during the introduction (in line with Clause 9.10) and again immediately before the sponsor's slot in the webinar. On this occasion, the Daiichi-Sankyo logo was visible on the first webinar slide to prompt the speaker to acknowledge the funding. It was also visible on the slides in the screenshots provided by the complainant. Additionally, Daiichi-Sankyo ensured that the sponsored sessions were clearly labelled as such, and in this regard it noted an email commenting on a draft version of the agenda (copy provided).

Daiichi-Sankyo stated that its investigations had revealed that the named consultant pharmacist was engaged by Daiichi-Sankyo in May 2019 to help review and further develop the company's PowerPoint presentation slides aimed at primary care/GP audiences. Some of those slides were identified from the screenshots provided by the complainant. The named consultant pharmacist had used some of the slides she helped review and develop in 2019 in his/her clinical presentation on 8 July 2020, 'Anticoagulation in complex patients'. Daiichi-Sankyo submitted, however, that it had not given the named consultant pharmacist those slides for the purpose of that (or any other) presentation. PowerPoint just happened to be the medium in which the information had been collated.

Neither Daiichi-Sankyo nor the medical education company gave permission for the slides to be used in the talk. However, even if Daiichi-Sankyo had, the complainant referred to the placement of the video on social media, not the use of the slides *per se*.

Daiichi-Sankyo contacted the named consultant pharmacist and he/she had confirmed the unauthorised use of the company's materials for the purpose of his/her presentation (copy provided).

Social media visibility

Daiichi-Sankyo submitted that neither it nor the medical education company had uploaded the slides to YouTube for public viewing. The company explained that part of the functionality of YouTube was that the infrastructure could be used in various ways by development companies and agencies; both as a viewing platform for live events; and to temporarily or permanently store information that they had developed. The medical education company had linked its webinar to YouTube. (A link to a video which showed how YouTube themselves explained the technology was provided).

In effect, the medical education company used an unlisted YouTube channel to store the recording so that it could edit it and provide a version to the delegates. As previously indicated, the medical education company did not have agreement from Daiichi-Sankyo for that, however, Daiichi-Sankyo had no editorial control over the named consultant pharmacist's presentation anyway.

Under normal circumstances the recordings (of the non-sponsored elements) were then uploaded as a pdf link to the delegate's dashboard.

The recordings could not be accessed by the general public, or anyone else, unless they had the direct link; and the link was only provided to delegates who attended.

The medical education company had confirmed that no recordings related to Daiichi-Sankyo funded events were visible on the educational platform.

Daiichi-Sankyo submitted that this meant that the only way that the recording could have been visible in the public domain was if someone hacked the medical education company website or the YouTube Channel; or it was placed/shared by a webinar delegate. There was no evidence of hacking and neither the medical education company nor Daiichi-Sankyo believed the recording was ever in the public domain.

Daiichi-Sankyo noted that the screen shots provided by the complainant clearly stated: '*Unlisted*'. This meant the video link was from an unlisted account and was not visible by anyone unless they had been given access to the link. The only people with access to the link were the delegates attending the event (who were all confirmed as health professionals).

Daiichi-Sankyo further noted that the side bar in the screen shots provided by the complainant showed music videos and submitted that in a genuine public search on YouTube for 'anticoagulation' videos, the sidebar would show videos related to anticoagulation; it would not show music videos. This meant the access to the medical education company recording shown in this screen shot had been obtained by following the link provided to the health professional delegates.

Daiichi-Sankyo noted that in the screenshots provided by the complainant, the text used in the search was not shown. Only the link was shown; this typically meant that the user had direct access to the specific page hosting the recording (ie it was accessed via a direct link, not a search). The medical education company had checked the link and had confirmed that it was the same link sent to delegates via their registered accounts. It was not a publicly available link.

Daiichi-Sankyo noted that if the link had been entered into Google, the recording would have been visible, but only registered delegates had the link.

The link was the medical education company's intellectual property and should have only legally been shared under the authority of the medical education company.

Daiichi-Sankyo stated that it concluded that the video was not publicly visible and that claims that it was were not true.

Alleged breaches

Daiichi-Sankyo stated that it played no role in the creation of the recording or the specific presentation featured in the recording. The presentation and recording were not sanctioned or approved by Daiichi-Sankyo, nor did they need to be. Accordingly, there was no breach of Clause 14.1 and the associated Clauses 14.5 and 14.6. (For clarity, Daiichi-Sankyo submitted that it did certify the presentations in the sponsored sessions.)

The material shown in the YouTube video was not promotional content created by or for Daiichi-Sankyo. Accordingly, Daiichi-Sankyo submitted that there was no breach of Clauses 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9 and 4.10. Nor was the material disguised promotion, so there was no breach of Clause 12.1.

(For clarity, Daiichi-Sankyo submitted that it did include appropriate mandatory information in the sponsored presentations and these were clearly labelled as Daiichi-Sankyo sessions.)

Daiichi-Sankyo's stated that its funding of the event was declared and the sponsored sessions were clearly labelled; Daiichi-Sankyo had no involvement in the creation or recording of the named consultant pharmacist's presentation, so the company denied breaches of Clauses 9.10 and 22.4.

The content of the named consultant pharmacist's presentation was not under the control of Daiichi-Sankyo, nevertheless the company believed that the medical education company's target audience of health professionals was appropriate for the content of his/her talk and the recording. The event itself was appropriately targeted at pharmacists. Daiichi-Sankyo denied a breach of Clause 11.1.

Daiichi-Sankyo did not pay the named consultant pharmacist, therefore denied a breach of Clause 23.1.

Daiichi-Sankyo submitted that the material was not placed in the public domain at all; therefore, there could not be a breach of Clauses 26.1 or 28.1. Regardless, Daiichi-Sankyo played no role in the creation or recording of the named consultant pharmacist's presentation, which was the only presentation subject to this complaint.

Daiichi-Sankyo categorically denied a failure to maintain industry standards and reputation in relation to this event. Both Daiichi-Sankyo and the medical education company had acted appropriately and professionally. Daiichi-Sankyo denied a breach of Clauses 9.1 or 2.

Conclusion

Daiichi-Sankyo stated that it hoped this full and frank account of events would confirm its strong conviction that it had not breached the Code.

Daiichi-Sankyo stated that it had funded an activity at arms-length in good faith. Daiichi-Sankyo did not influence the speaker to include product slides. Neither Daiichi-Sankyo nor the medical education company knowingly placed the recording in the public domain. Daiichi-Sankyo believed that on the balance of probabilities the complainant had deliberately engineered a story that created a false and misleading version of the true events.

PANEL RULING

The Panel noted Daiichi-Sankyo's submission that the YouTube video in question was of the medical education company - organised main clinical session from a meeting initiated and coordinated by the medical education company held on 8 July 2020. According to Daiichi-Sankyo it had provided sponsorship for the meeting and in return was able to provide speakers for some parts of the agenda.

The Panel noted that there were a number of ways that pharmaceutical companies could be involved in meetings organised by third parties including general sponsorship, sponsoring a specific part of it, or paying to exhibit.

The Panel noted Daiichi-Sankyo's submission that the agenda was split into a formal clinical session and several Daiichi-Sankyo sponsored sessions; the medical education company had selected half of the speakers and Daiichi-Sankyo had selected the other half. Daiichi-Sankyo stated that it had full control in selecting, briefing and contracting the speakers for its sponsored sessions. Daiichi-Sankyo did not have any involvement in identifying attendees for the event.

The Panel made its ruling on the basis of the five screenshots provided by the complainant.

The Panel noted Daiichi-Sankyo's submission that neither it nor the medical education company had uploaded the presentation onto YouTube for public viewing. The Panel noted that according to Daiichi-Sankyo the medical education company routinely recorded presentations made by its speakers and made the recordings available via a portal and delegate dashboard linked to the non-public YouTube infrastructure to those delegates. The medical education company used an unlisted YouTube channel to store the recording so that it could edit it and provide a version to the delegates. The Panel noted Daiichi-Sankyo's submission that the recordings could not be accessed by the general public, or anyone else, unless they had the direct link. The Panel noted Daiichi-Sankyo's submission that the only people with access to the link provided by the complainant were the delegates attending the event who were all confirmed as health professionals. The Panel noted that according to comments from the medical education company, which were provided by Daiichi-Sankyo, if the link was entered into a Google web browser that search would, nonetheless, identify the video in question.

It appeared to the Panel that the video in question could only be accessed via a specific link which had only been made available to delegates. On the limited information before the Panel, it appeared unlikely, on the balance of probabilities, that the video would be accessed by searching YouTube or the wider internet. The Panel also bore in mind Daiichi-Sankyo's submission that the screenshots of the video in question provided by the complainant appeared to have been accessed by the link provided to delegates. The Panel considered that the complainant had not established, on the balance of probabilities, that the publication of the video in question on YouTube meant that it was available to the public as alleged. In any event, it appeared that Daiichi-Sankyo had no role whatsoever in relation to the publication of the video in question. No breach of Clauses 26.1 and 28.1 were ruled.

The Panel noted Daiichi-Sankyo's submission that the target audience of the meeting was pharmacists and the content of the recording was appropriate for that audience. Noting its comments above about the publication of the video the Panel did not consider that the complainant had provided evidence that the recording had been sent or distributed by Daiichi-Sankyo to anyone whose need for or interest in it could not be reasonably assumed and no breach of Clause 11.1 was ruled.

The Panel noted Daiichi-Sankyo's submission that whilst it certified the presentations in its company sessions, it did not initiate or influence the content of the presentation in the video in question, did not choose the speaker and therefore did not review the slides. The Panel noted that the speaker in the video in question had access to Daiichi-Sankyo slides from a different project and had, without the company's permission, used some of those slides in the presentation in question which was not under Daiichi-Sankyo's control. The Panel noted

Daiichi-Sankyo's submission that it had included the appropriate mandatory information in its presentations, however, the material shown in the video in question was not promotional content created by or for Daiichi-Sankyo. The Panel considered, on the evidence before it, that Daiichi-Sankyo was not responsible for the content of the presentation in question in relation to the Clauses cited and, in that regard, ruled no breach of Clauses 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 4.10, 12.1, 14.1, 14.5 and 14.6.

The Panel noted Daiichi-Sankyo's submission that it did not choose the speaker or initiate or influence the content of the presentation shown in the recording. Nor had the company paid the speaker in question in relation to his/her presentation. The Panel therefore ruled no breach of Clause 23.1.

The Panel considered that Daiichi-Sankyo had been badly let down by the speaker of the presentation in question who had been a consultant of Daiichi-Sankyo's in a previous project and had re-purposed Daiichi-Sankyo material in his/her presentation without the company's permission and this had contributed to the misleading impression that Daiichi-Sankyo was involved with the content of that particular session which was not so. Furthermore, the medical education company appeared not to have followed its own standard policies on this occasion as it did not review the slides from the presentation in question and the moderator did not intervene to prevent any 'un-reviewed' slides from being displayed. It was a well-established principle that companies were responsible under the Code for the acts and omissions of its consultants and third parties working on its behalf. However, the Panel noted, that in this particular case, the speaker in question was not acting as a consultant to the company and the medical education company was not working on Daiichi-Sankyo's behalf. Daiichi-Sankyo had provided sponsorship to the medical education company for the entire meeting and in return Daiichi-Sankyo was able to provide speakers for some sessions on the agenda. Those sessions were labelled as optional and signposted on the agenda as 'Sponsored by Daiichi-Sankyo'. The Panel noted that according to Daiichi-Sankyo delegates had to visit a separate virtual room to access these sessions and in the Panel's view, Daiichi-Sankyo was responsible under the Code for the content of these sessions. The Panel considered, however, that in the particular circumstances of this case Daiichi-Sankyo was not responsible for the content of the independent sessions that it had no influence on, which included the session in the YouTube video in question. The Panel noted its comments above and considered that there was no evidence to show that Daiichi-Sankyo had failed to maintain high standards in that regard and no breach of Clause 9.1 was ruled.

The Panel noted that Clause 9.10 stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. The supplementary information stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. Clause 22.4 stated that when meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

The Panel noted that Daiichi-Sankyo's logo appeared on two slides of the presentation at issue provided by the complainant; the first slide and the slide displaying the agenda for the whole

meeting. Further, four of the slides discussing edoxaban were Daiichi-Sankyo branded slides. Whilst noting Daiichi-Sankyo's submission that the speaker re-purposed material from a different Daiichi-Sankyo project without the company's permission and that the Daiichi-Sankyo sessions at the virtual meeting in question were signposted as such, it did not consider that Daiichi-Sankyo's sponsorship of the meeting overall and its lack of involvement in the particular session was sufficiently clear from the outset of the presentation. A company logo was considered insufficient in this regard and a verbal briefing about sponsorship did not negate the need for a written unambiguous declaration of sponsorship. Further, the Panel did not know what was said in the verbal briefing. Breaches of Clauses 9.10 and 22.4 were ruled. High standards had not been maintained in that regard and a breach of Clause 9.1 was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted its comments and rulings above and did not consider that the particular circumstances of this case warranted a ruling of this clause and therefore no breach of Clause 2 was ruled.

APPEAL BY THE COMPLAINANT

The complainant appealed the Panel's ruling of no breach of Clause 2.

The complainant alleged that it was ironic that in attempting to mention that he/she had given the Panel false information, Daiichi-Sankyo had given the Panel false information. On November 9 he/she had sent the Panel his/her complaint email with six screenshots of the YouTube video. None of these screenshots included this 'side bar' with 'music videos' that Daiichi-Sankyo mentioned that he/she supposedly provided in its response. The complainant noted that Daiichi-Sankyo had even gone to the trouble of circling in red this side bar, which certainly did not come from him/her and was completely irrelevant to his/her complaint. Why had Daiichi-Sankyo given the Panel this false information that he/she provided a screenshot with a side bar with music videos? The complainant alleged that Daiichi-Sankyo argued for some reason that the music videos in the side bar meant that the video was accessed by him/her using a link provided to the health professional delegates. But in fact it was the company's own screenshot, and it must be Daiichi-Sankyo who accessed the video in that way. The complainant stated that he/she believed Daiichi-Sankyo had deliberately misled the Panel by saying that he/she had provided the screenshot in order to try to strengthen its case regarding how the video was accessed.

The complainant alleged that providing the Panel with such false information surely fitted the criteria for a Clause 2 breach. It was so blatant, it was easy to see what six screenshots the complainant had provided; he/she queried how Daiichi-Sankyo could submit that he/she had provided a completely different screenshot.

The complainant noted that another reason for the appeal of the ruling of no Clause 2 was transparency. The complainant alleged that it was not at all clear on the video what the company's involvement was, in fact that was what prompted his/her complaint in the first place. It was vital that the viewers of such videos knew exactly what influence pharmaceutical companies had had so they could form a proper judgement on the content. This principle of transparency had been in place for many years and if companies still did not understand their obligations, this must be serious enough to state that Clause 2 had been breached.

RESPONSE FROM DAIICHI-SANKYO

Daiichi-Sankyo submitted that it would like to sincerely apologise to the Panel and the complainant. Daiichi-Sankyo had mistakenly assumed that the Panel's screenshot was one of the screenshots provided by the complainant. Daiichi-Sankyo understood this error had caused distress, disappointment, and inconvenience. Daiichi-Sankyo expressed its sincere apologies, and thanked the Panel for bringing this to its attention.

Daiichi-Sankyo submitted that the Panel had made the correct rulings, including the decision that the circumstances of this case did not warrant a ruling of a breach of Clause 2. The Code noted that Clause 2 was a sign of particular censure and reserved for such use. The Code listed examples of activities that were likely to be in breach of Clause 2 such as prejudicing patient safety and/or public, health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time. This case did not fall under the circumstances that warranted a Clause 2 ruling.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant had no final comments.

APPEAL BOARD RULING

The Appeal Board noted that the Panel had ruled breaches of the Code (Clauses 9.10 and 22.4) as well as a breach of Clause 9.1, for failing to maintain high standards, as Daiichi-Sankyo's sponsorship of the meeting overall and its lack of involvement in the particular session at issue was not sufficiently clear from the outset. The Appeal Board noted the Panel had considered that Daiichi-Sankyo had been badly let down by the speaker of the presentation in question, and the Appeal Board agreed with that assessment. These rulings had not been appealed.

The Appeal Board noted that Clause 2 was a sign of particular censure and reserved for such use. The Appeal Board did not consider that in the particular circumstances of this case a breach of Clause 2 was warranted. In the Appeal Board's view, the complainant's concerns were adequately covered by the Panel's ruling of a breach of Clause 9.1. The Appeal Board upheld the Panel's ruling of no breach of Clause 2. The complainant's appeal was unsuccessful.

Complaint received **9 November 2020**

Case completed **27 May 2021**