CASE AUTH/3409/10/20

COMPLAINANT v DAIICHI-SANKYO

Promotional Lixiana email and video

An anonymous, non-contactable complainant who described him/herself as a concerned health professional, alleged numerous breaches of the Code with regard to a promotional email and video that had been sent to a patient by Daiichi-Sankyo UK Ltd. The email was signed by the Lixiana team at Daiichi-Sankyo Europe. Lixiana (edoxaban) was an anticoagulant indicated to prevent stroke and systemic embolism in certain adults with nonvalvular atrial fibrillation (NVAF).

The email, with the subject heading 'Lixiana Presents -The Evidence - Series 1 / Episode 1', introduced the 'Dear Healthcare Professional' reader to a series of videos the first of which would outline the clinical evidence for treating elderly NVAF patients with a NOAC [novel oral anticoagulant] and examine the robustness of the Lixiana clinical trials and its efficacy and safety profile. A visual at the top of the email included a montage of one person with a number of otherwise disembodied heads; to the left of that appeared the Lixiana logo including the non-proprietary name and 'Welcome to the evidence' above the title of the first episode, 'The proven choice'.

The complainant submitted that his/her patient (the recipient) had never agreed to receive such emails and alleged that it clearly promoted to the public and added that even if the email had been sent to him/her as a health professional it should not have had 'Lixiana' in the title without the generic name. The complainant further noted that the email did not state that it was promotional, there was no declaration of sponsorship or link to prescribing information or any adverse event reporting statement and he/she alleged that the claim, 'proven choice', was unsubstantiated. The complainant stated that these allegations also applied to the video and that it, in addition, contained claims of 'ideal' and off-label information about dosing.

The complainant alleged that the picture of the heads was not appropriate for patients and was in poor taste. The complainant queried whether the material had been approved and if any contracts and payments to the UK doctors who appeared in the video were approved and correct and had been disclosed.

The complainant stated that he/she had received two more emails and videos, ie a total of six promotional materials, all with the same breaches.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that the email was part of a campaign initiated by Daiichi-Sankyo Europe and conducted, via an agency, without the UK's knowledge. The email provided by the complainant appeared to be an invitation to watch the first of a series of videos regarding Lixiana in the treatment of elderly NVAF patients;

according to Daiichi-Sankyo the campaign leveraged videos created in 2018 for another Daiichi-Sankyo Europe project that Daiichi-Sankyo UK had known about.

The Panel noted that the hard copy of the email provided by the complainant differed from that provided by Daiichi-Sankyo. The complainant's copy finished at 'Kind Regards, Your Lixiana Team from Daiichi-Sankyo Europe' and stated 'RESTRICTED' in the bottom right-hand corner of the page. The email provided by Daiichi-Sankyo had a short video embedded within it and the European prescribing information within the body of the email. The Panel further noted Daiichi-Sankyo's assertion that the materials submitted by the complainant were incomplete and misleading. The complainant had, however, referred to both an email and video being sent to his/her patient.

The complainant's statement that he/she had received two further emails and videos appeared inconsistent with his/her initial comment that the original email in question had been sent to a patient. It was not clear to the Panel if the complainant's patient had also received the second and third emails. The complainant did not provide copies of the further two emails and videos but these were provided as part of Daiichi-Sankyo's response. As the complainant was non-contactable the Panel could not contact him/her for further information.

The Panel based its rulings on the first email of the campaign, part of which was provided by the complainant, and the associated video provided by Daiichi-Sankyo, as well as the third video in the series in relation to the complainant's allegation regarding use of the claim 'ideal'.

The Panel noted Daiichi-Sankyo's submission that for the email campaign in question, Daiichi-Sankyo Europe instructed its agency to only target cardiologists. The Panel noted Daiichi-Sankyo's submission regarding the agency's process to ensure that those who signed up to access its website/join its database had declared themselves to be health professionals; an additional, explicit opt-in for receiving promotional emails was solicited, and such emails might only be sent to those health professionals who had opted in. The Panel noted the information that was requested by the agency upon registration including a medical licence number for UK health professionals and that that requirement was only provisionally removed after the email campaign in question.

The Panel noted Daiichi-Sankyo's submission that, during the course of a previous engagement with Bayer, the agency had manually added two Bayer employees to its database, at the employees' request, and that their details were mistakenly not removed after the project with Bayer had ended. The Panel, noted, however, that Bayer had contacted Daiichi-Sankyo in September 2020 to complain about the email campaign which was immediately stopped the following day. It appeared that between Bayer and Daiichi-Sankyo the matter had been dealt with under inter-company dialogue. The Panel further noted that the complaint concerned receipt of the email in question by a specific patient, the complainant did not make a general direct or indirect allegation about the broader distribution of the email in question. Whilst the Panel was concerned about receipt of the email in question by two Bayer employees it decided on balance that that matter did not fall within the scope of the complaint and thus it would make no ruling about that matter.

The Panel noted that the Code's requirement that permission must be obtained from a recipient prior to promoting via email only applied to health professionals and other relevant decision makers. The Panel noted the complainant's statement that his/her patient (the recipient) had never agreed to receive such emails. The complainant had not revealed the professional status or otherwise of the patient and that he/she bore the burden of proof in that regard. In the Panel's view the complainant had not established on the balance of probabilities that the email in question, or the other two emails that he/she referred to, had been received by a health professional without his/her prior permission; the complainant only referred to the first email being received by his/her patient without permission and the provisions of the Code did not apply to that allegation. No breach of the Code was ruled.

The Panel noted that the Code required mailing lists to be kept up to date and requests to be removed from promotional mailing lists must be complied with promptly. In that regard, noting its comments above, the Panel did not consider that those provisions of the Code applied to the complainant's allegation regarding his/her patient; no breach of the Code was ruled. Furthermore, the Panel noted Daiichi-Sankyo's submission that whilst both Bayer employees received the first email of the campaign, one employee subsequently opted out and did not receive the second and third emails which demonstrated that the opt-out process functioned as intended.

The Panel noted that the Code 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 Panel noted that the complainant had not stated whether his/her patient who had received the email was a health professional such that one could determine whether the material was tailored to the audience. On the evidence available, the Panel ruled no breach of the Code.

The Panel noted Daiichi-Sankyo's submission that aside from the two Bayer employees, noted above, all of the database registrants and thereby recipients of the email campaign in question would have provided medical licence numbers and declared themselves to be health professionals. The Panel noted that receipt of the email by two Bayer employees was covered by its decision above. The Panel also noted its comments above that the opt-out facility appeared to function as intended, and that the complainant had not provided any evidence as to the professional status of his/her patient. The Panel noted that the complainant had not established, on the balance of probabilities, that members of the public had received the email and no breaches of the Code were ruled.

The Panel noted that the Code required material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which was sponsored by a pharmaceutical company to clearly indicate that it has been sponsored by that company. The Panel noted that the subject line of the email in question stated 'Lixiana Presents -The Evidence - Series 1 / Episode 1'; 'Daiichi-Sankyo' was named as the sender of the email and the email domain was that of the third-party agency. The Panel further noted that the email was signed by 'Your Lixiana Team from Daiichi-Sankyo Europe'. As noted above, the material provided by the complainant and that provided by the company differed in that the email provided by the company appeared to be complete and the Panel therefore considered the allegation in relation to the material as provided by the company. The email provided by the company included the Lixiana European prescribing information and the Daiichi-Sankyo logo on the last

page. In the Panel's view it was sufficiently clear that the email was promotional material from Daiichi-Sankyo and no breaches of the Code were ruled.

The Panel noted that the email did not include 'edoxaban' immediately adjacent to the brand name at its first appearance and that it also did not include the adverse events reporting statement or the date upon which the material was drawn up or last revised. Breaches of the Code were ruled as acknowledged by Daiichi-Sankyo.

With regard to the provision of prescribing information, the copy of the email provided by Daiichi-Sankyo included the European prescribing information which the Panel noted did not appear to include the UK cost of the medicine as required. Breaches of the Code were ruled in relation to the email and the video.

The Panel noted that while the complainant had alleged that the visual of a patient with multiple heads was inappropriate for patients, Daiichi-Sankyo submitted that the material was not targeted at patients and although the visual was designed to be arresting, it was selected based on market research conducted with an appropriate audience ie health professionals. The Panel did not consider that the complainant had established that use of the image meant that Daiichi-Sankyo had failed to maintain high standards and no breach was ruled.

The Panel noted that in the third video in the series titled 'Lixiana in challenging NVAF patients – Practical benefits' the speaker referred to edoxaban as 'ideal'. In addition, during the presentation a box in the top left-hand side of the screen stated 'Edoxaban is ideal for elderly patients at risk of bleeding'. The Panel noted Daiichi-Sankyo's submission that it did not defend such use of the word 'ideal'. The Panel further noted Daiichi-Sankyo's submission that use of 'the proven choice' as the title of the first video and within the email at issue was not in accordance with UK standards; that 'the proven choice' referred to the quantity and consistency of clinical and real-world evidence available for edoxaban had not been made sufficiently clear and might be interpreted as an implied comparison with other medicines and was thus not capable of substantiation. The Panel therefore ruled breaches of the Code as acknowledged by Daiichi-Sankyo.

The Panel noted Daiichi-Sankyo's submission that the first video in the email in question referred to a Lixiana clinical trial which included a 'low dose' treatment arm, which was not in-label. Daiichi-Sankyo submitted that either it should have omitted the information or made it clear that that was not a licensed dose. The Panel ruled a breach of the Code as acknowledged by the company.

The Panel noted Daiichi-Sankyo's submission that its European affiliate had not briefed it on the email campaign and had not got the campaign certified in accordance with the Code before it was launched and no certificate existed. The Panel therefore ruled a breach of the Code as acknowledged by the company. The Panel noted that although the complainant had cited a clause of the Code which related primarily to the content of an approval certificate, his/her allegation referred to approval of the material rather than the content of the certificate. The Panel thus decided that the clause cited was not applicable and no breach was ruled.

The Panel noted that the complainant had queried whether the contracts and payments for the UK health professionals who appeared in the videos had been approved and the

payments disclosed. The Panel noted Daiichi-Sankyo's submission that the videos had been adapted from those originally made in 2018. The UK company knew about the 2018 project and it examined and approved the contracts for the two UK health professionals involved; the contracts were signed by Daiichi-Sankyo Europe as well as by the two consultants. The Panel did not have a copy of the contracts before it. The complainant had not provided evidence to show that the contracts with the consultants were in breach of the Code as alleged and no breach was ruled. Further, despite multiple reminders, the health professionals had not yet submitted valid invoices for their services and had thus not been paid. The Panel noted there were thus no transfers of value to declare and therefore ruled no breaches of the Code.

The Panel noted its comments and rulings of breaches of the Code above and considered that Daiichi-Sankyo had failed to maintain high standards; a breach of the Code was ruled.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted that examples of activities likely to be in breach of that clause, as listed in the supplementary information, included prejudicing patient safety. The Panel noted its rulings above, particularly in relation to not including a statement regarding the reporting of adverse events and the reference to a an unlicensed 'low-dose' of edoxaban and considered that Daiichi-Sankyo had reduced confidence in and brought discredit upon the industry; the Panel ruled a breach of Clause 2.

An anonymous, non-contactable complainant who described him/herself as a concerned healthcare professional, complained about a promotional email and video that had been sent to one of his/her patients by Daiichi-Sankyo UK Ltd. The email was signed by the Lixiana team at Daiichi-Sankyo Europe.

Lixiana (edoxaban) was an anticoagulant indicated to prevent stroke and systemic embolism in certain adults with nonvalvular atrial fibrillation (NVAF).

The subject line of the email read 'Lixiana Presents -The Evidence - Series 1 / Episode 1'. A visual at the top of the email included a montage of one person with a number of otherwise disembodied heads, to the left of which appeared the Lixiana logo including the non-proprietary name and 'Welcome to the evidence' above the title of the first episode, 'The proven choice'.

The email was addressed 'Dear Healthcare Professional' and told the reader that the first video in a series of short interviews with international renowned experts in the field of cardiology would outline the current understanding of clinical evidence for treating elderly NVAF patients with a NOAC [novel oral anticoagulant] and that in the video a named consultant cardiologist would examine the robustness of the Lixiana clinical trials and its efficacy and safety profile as demonstrated in the ENGAGE-AF trial.

COMPLAINT

The complainant submitted that his/her patient (the recipient) had never agreed to receive such emails and always declined junk mail. The complainant alleged breaches of Clauses 9.9, 11.1 and 11.3.

The complainant alleged that this was clearly promotion to the public in breach of Clauses 26.1 and 26.2.

Even if the email had been sent to him/her as a health professional it should not have had 'Lixiana' in the title without the generic name; the complainant alleged a breach of Clause 4.3. The complainant further noted that it did not say that it was promotional and there was no declaration of sponsorship. Breaches of Clauses 9.10 and 12.1 were alleged.

The complainant further noted that there was no link to prescribing information or any adverse event reporting statement in breach of Clauses 4.4, 4.5, 4.9; and that the claim of 'proven choice' was unsubstantiated in breach of Clauses 7.2, 7.3, 7.4 and 7.10.

The complainant stated that the allegations above also applied to the video and so that was also in breach of the same clauses as well as containing further claims of 'ideal' and off-label information about dosing in breach of Clauses 3.2, 7.2, 7.3, 7.4 and 7.10.

The complainant alleged that the picture of the heads was not appropriate for patients and was in poor taste in breach of Clause 9.1.

The complainant stated that there was no UK reference code or date on the email and as it was sent to a UK audience it did not look like it went through any kind of approval in breach of Clauses 4.1, 4.8, 14.1 and 14.5. This was strange as a number of UK doctors were in the videos and so the complainant queried if any contracts and payments were approved and correct. He/she considered that there was a potential breach of Clauses 23.1 and 23.2 as well as of Clauses 24.1 and 24.2 with regard to disclosure.

The complainant stated that he/she had received two further emails and videos making a total of six promotional materials all with the same breaches. This was totally unacceptable behavior and was a breach of Clauses 9.1 and 2.

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

RESPONSE

Daiichi-Sankyo stated that it was deeply disappointed about the allegations and grateful for the opportunity to respond. Daiichi-Sankyo had integrity as one of its core values and it took ethics and compliance extremely seriously. While Daiichi-Sankyo was not perfect, the company was working to strengthen the understanding of compliance, particularly Code compliance, across the organisations and its efforts had the full attention and support of the Daiichi-Sankyo Europe GmbH managing board.

Background: Inter-company dialogue

Daiichi-Sankyo stated that on the evening of 2 September 2020, Bayer UK contacted Daiichi-Sankyo UK to complain about the email campaign in question. The campaign was immediately stopped on 3 September, issues and root causes were investigated, and the final CAPA (Corrective and Preventative Action) plan was communicated to Bayer.

Daiichi-Sankyo explained that the email campaign in question was initiated by Daiichi-Sankyo Europe and conducted by an external agency without the knowledge of, and consequently also without any certification by, Daiichi-Sankyo UK; that important step of the process was omitted by Daiichi-Sankyo Europe in error. The email campaign leveraged existing videos which were created in 2018 for another Daiichi-Sankyo Europe project which had been conducted with the knowledge of Daiichi-Sankyo UK; all health professional contracts and briefing documents had been examined and certified by Daiichi-Sankyo UK, as required.

For the current email campaign, Daiichi-Sankyo Europe instructed its agency to target cardiologists. Daiichi-Sankyo provided a timeline of activity in relation to the campaign which started on 12 August 2020 with the sending of the first email (the second and third emails were sent on 19 and 26 August) and was stopped on 3 September. Bayer contacted the agency on 17 August to inquire about the first email (the agency did not inform Daiichi-Sankyo Europe about that contact) and on 2 September Bayer contacted Daiichi-Sankyo UK (the first time Daiichi-Sankyo UK knew about the campaign).

Daiichi-Sankyo submitted that the agency had a robust process in place to ensure that those who signed up to access its website/join its database had declared themselves to be health professionals. The restriction of access to health professionals was referenced several times during the sign-up process, and health professional identification numbers were required as well (though not required anymore since October 2020). An additional, explicit opt-in for receiving promotional emails was solicited, and such emails might only be sent to those health professionals who had opted in. (The copy of the submission by the agency contained further details about the general sign-up and opt-in process).

Daiichi-Sankyo explained however, that during the course of the engagement with Bayer, the agency manually added two Bayer employees to its database, at the employees' request; the health professional status of those employees was not definitively known to Daiichi-Sankyo UK. The Bayer employees were mistakenly not removed from the database after the project with Bayer had ended and both received the first email of the Daiichi-Sankyo Europe campaign. One employee subsequently opted out and so only the other one received the second and third emails. Aside from the Bayer employees, all of those registered on the agency database had provided medical licence numbers and declared themselves to be health professionals.

Actions and remediation plan

Based on the findings described above, the following corrective actions were taken by Daiichi-Sankyo Europe including that the campaign was immediately stopped and on 3 September 2020 all related materials were taken offline.

A senior manager at Daiichi-Sankyo Europe, upon being informed of the issue, sent an email on 10 September 2020 addressing the situation. Specifically, Daiichi-Sankyo Europe was not to send any communications directly or through agencies to UK health professionals, that any EU or global communication directed to UK health professionals needed to be cleared upfront by the UK compliance team and that any EU or global communication directed to UK health professionals would be distributed only if approved by the UK organisation in line with the Code. The email was also sent to the global organisation to further ensure similar mistakes could be avoided in the future.

The agency had acknowledged that it had let Daiichi-Sankyo down. All Bayer employees had now been removed from the agency's database, the agency had implemented a number of measures to avoid a similar mistake in the future and its employees had been trained on the Code in October.

Daiichi-Sankyo Europe had further undertaken to retrain its marketing and medical organisations on 'Compliance in a European setting.' The training had been developed with and was being delivered by a Code expert and covered topics including the need to obtain local approvals, requirements for materials/claims, the difference between promotional and non-promotional activity and responsibilities when working with third parties. The first training session took place in October and November 2020.

Finally, Daiichi-Sankyo Europe had undertaken to link its materials approval system more closely with the affiliates.

Daiichi-Sankyo stated that the aforementioned CAPA actions were communicated to Bayer on 6 October 2020 and on 20 October it notified Daiichi-Sankyo UK that it was satisfied with the response and considered the matter closed.

Daiichi-Sankyo was devastated to learn about the complaint, particularly as the company, having been alerted to the matter by Bayer, had put corrective actions in place to ensure such mistakes did not occur again. Daiichi-Sankyo therefore hoped that the Panel would take the inter-company dialogue and CAPA plan into account when considering the allegations.

Clause 9.9

With regard to the use of email, Daiichi-Sankyo denied a breach of Clause 9.9, in reliance on the agency's opt-in process, as well as the fact that Bayer employees requested to be added to the distribution list.

Specifically, considering the agency's sign-up process, particularly the requirement to actively opt-in to receive promotional emails, Daiichi-Sankyo submitted that it was highly unlikely that people would have joined the agency's database and received emails without providing their consent.

The continued presence of Bayer employees in the database was a mistake and not the result of deliberate and systematic failings; furthermore, one Bayer employee did not opt-out after the first email, indicating his/her interest in continuing to receive the emails.

Clause 11.1

With regard to the targeting of the material, Daiichi-Sankyo denied a breach of Clause 11.1, in reliance on the agency's robust opt-in process.

Specifically, considering the agency's sign-up process, particularly the requirement to actively opt-in to receive promotional emails, it was highly unlikely that people would have received emails without having indicated interest in receiving such material.

While the inclusion of Bayer employees to the distribution list was an error, Bayer's interest in receiving competitor materials could be reasonably assumed (though it was generally not in Daiichi-Sankyo's interest to share them in such a manner).

Clause 11.3

With regard to keeping mailing lists up-to-date, Daiichi-Sankyo UK denied a breach of Clause 11.3, in reliance on the agency's opt-out process. Daiichi-Sankyo acknowledged that the agency made a mistake in keeping two Bayer employees in the database. The opt-out process however functioned as intended, since recipients of promotional emails, including the Bayer employee who opted-out after the first email, were immediately removed, and did not receive any further emails.

Clause 26.1

Daiichi-Sankyo noted that it was not the intention to use the email campaign to advertise prescription only medicines to the public. Indeed, the salutation of the email ('Dear healthcare professional') demonstrated that the intent was to promote only to physicians and in that regard Daiichi-Sankyo Europe instructed the agency to only target cardiologists.

Additionally, in light of the agency's sign-up process, particularly the requirement to submit medical licence numbers during registration, Daiichi-Sankyo considered that it was highly unlikely that patients or members of the public would have joined the agency's database and received emails without fraudulently claiming to be health professionals as well as opting-in for promotional emails (with the noted exception of the two Bayer employees). Without proof that members of the public had access to the materials, Daiichi-Sankyo denied a breach of Clause 26.1.

While acknowledging that two Bayer employees received the first email in the campaign, this was done in error and Daiichi-Sankyo had no definitive knowledge or evidence about their health professional status.

Clause 26.2

With regard to provision of information to the public, Daiichi-Sankyo denied a breach of Clause 26.2 as there was no intent to provide information to the public either directly or indirectly, nor was there intent to promote prescription medicines to the public, raise hopes for successful treatment, or encourage members of the public to ask their doctor for a specific medicine. Daiichi-Sankyo reiterated that there was no proof that members of the public had received the materials and it considered it highly unlikely that they would generally have had access.

While Daiichi-Sankyo acknowledged that two Bayer employees received the first email in the campaign, it was done in error and Daiichi-Sankyo had no definitive knowledge or evidence about their health professional status.

Clause 4.3

Daiichi-Sankyo acknowledged that the first instance of the brand name Lixiana, in the subject line of the email, should have been followed with the non-proprietary name, edoxaban; the company accepted that it had breached Clause 4.3.

Clause 9.10

With regard to sponsorship of the campaign, Daiichi-Sankyo denied a breach of Clause 9.10 as the email was clearly marked as being from the company in that the company was listed as the sender name and the email was signed by 'Your Lixiana Team from Daiichi-Sankyo Europe'

Clause 12.1

Daiichi-Sankyo Europe had not claimed that the content of the email was non-promotional, nor sought to disguise the promotional nature of the email. Indeed, the promotional nature of the material was clear from the subject line, which referred to the brand name Lixiana. Daiichi-Sankyo denied a breach of Clause 12.1.

Clauses 4.1, 4.4 and 4.5

With regard to the provision of prescribing information, Daiichi-Sankyo noted that it had submitted a copy of the full email campaign in question and so it should be clear that the materials submitted by the complainant were incomplete and misleading. The European prescribing information was included at the end of the message in a clear, legible, and easily referenced manner although Daiichi-Sankyo acknowledged that the UK prescribing information differed slightly from the European version. That error ultimately stemmed from the failure to request UK certification, rather than a failure to include prescribing information altogether. The company denied breaches of Clause 4.1, 4.4 and 4.5.

Clause 4.9

Daiichi-Sankyo acknowledged a breach of Clause 4.9 in that the adverse events reporting statements required by the Code were missing.

Clauses 7.2, 7.3, 7.4 and 7.10

Daiichi-Sankyo acknowledged that the use of 'proven' and 'ideal' in the first email of the campaign was not in accordance with UK standards and practice. The claim of 'proven' referred to the quantity and consistency of the clinical and real-world evidence available for edoxaban; that had not been made sufficiently clear in the materials and might be interpreted to be an implicit comparison with other medicines and was not capable of substantiation.

Daiichi-Sankyo did not defend Daiichi-Sankyo Europe's use of the word 'ideal' and acknowledged breaches of Clauses 7.2, 7.3, 7.4 and 7.10.

Clause 3.2

Daiichi-Sankyo acknowledged that the first video referred to a Lixiana clinical trial which included a 'low dose' treatment arm, which was not in-label. However, the video did not advocate using the low-dose regimen; the information was included to provide a comprehensive overview of the clinical trial. In hindsight, Daiichi-Sankyo acknowledged that either it should have omitted the information or made it clear that that was not a licensed dose. The company acknowledged a breach of Clause 3.2.

Clause 9.1

Daiichi-Sankyo noted the allegation that the visual of a patient with multiple heads was inappropriate for patients, in breach of Clause 9.1 but submitted that the material was not targeted at or meant for patients, and there was no evidence that patients had viewed it. Additionally, although the visual was designed to be arresting, there was no nudity, partial nudity, sexual imagery, or the like, which was the standard set out in the supplementary information to Clause 9. The 'patient with multiple heads' was selected based on its performance in market research conducted with health professionals during the course of developing the material in 2018.

Clause 4.8

Daiichi-Sankyo acknowledged that Daiichi-Sankyo Europe had failed to include a date indicating when the promotional material was created or last revised. The company acknowledged a breach of Clause 4.8.

Clauses 14.1 and 14.5

Daiichi-Sankyo reiterated that its European affiliate had not briefed it on the email campaign and had failed to get it certified by the UK before it was launched. The promotional material was thus not certified in accordance with UK Code. No certificate existed, and therefore the certificate was not in compliance with requirements. The company acknowledged breaches of Clauses 14.1 and 14.5.

Clause 23.1

Daiichi-Sankyo reiterated that the videos which were adapted for the email campaign in 2020 were originally made in 2018 at the European Society of Cardiology (ESC). The 2018 project was known to the Daiichi-Sankyo UK organisation, and the contracts for both named health professionals were examined and approved by the UK medical department. (No certification was necessary: since both named health professionals were already in attendance at ESC, the contracts involved only honoraria.). The contracts were signed at the ESC by representatives of Daiichi-Sankyo Europe as well as by the two consultants. Daiichi-Sankyo denied a breach of Clause 23.1.

Clauses 23.2, 24.1 and 24.2

Daiichi-Sankyo submitted that a review of its and of Daiichi-Sankyo Europe's financial records, showed that despite multiple reminders, the health professionals had not yet submitted valid invoices for their services and had thus not been paid and so no reporting had been made. The company denied breaches of Clauses 23.2 and 24.1 and 24.2.

Summary

Daiichi-Sankyo acknowledged that the Daiichi-Sankyo Europe email campaign, in particular Daiichi-Sankyo Europe's fundamental error not to engage the UK in the prior review and certification of the campaign, resulted in breaches of the Code. This mistake was further exacerbated by mistakes made by Daiichi-Sankyo Europe's agency.

Daiichi-Sankyo UK and Daiichi-Sankyo Europe sincerely apologized for the errors made. The companies had acted quickly to stop the campaign as soon as they were aware of the issue and

had taken steps to prevent similar mistakes from occurring in the future. In particular, Daiichi-Sankyo Europe had re-trained its entire medical and marketing teams about the need to obtain approvals from local organisations, requirements for materials and claims, the difference between promotion and non-promotion, and responsibilities when working with third parties. Additionally, Daiichi-Sankyo had upgraded its systems to enable European teams to more efficiently obtain materials feedback/approvals from local organisations.

Daiichi-Sankyo noted that both the UK and Europe had taken this case extremely seriously from the very beginning. Starting already from the inter-company dialogue with Bayer, this case and its remediation had been closely monitored by the Daiichi-Sankyo Europe Managing Board, which was regularly updated on all developments.

Daiichi-Sankyo hoped that the speed with which it moved to investigate and remediate this case demonstrated its commitment to upholding high standards and showed that it had not brought discredit upon, nor reduced confidence in, the pharmaceutical industry. Daiichi-Sankyo denied breaches of Clauses 2 and 9.1.

PANEL RULING

The Panel noted Daiichi-Sankyo's submission that the email at issue was part of a campaign initiated by Daiichi-Sankyo Europe and conducted by its external agency without the knowledge of Daiichi-Sankyo UK. The Panel noted that the email provided by the complainant appeared to be an invitation to watch the first of a series of videos regarding Lixiana in the treatment of elderly NVAF patients and that the campaign leveraged videos created in 2018 for another Daiichi-Sankyo Europe project that Daiichi-Sankyo UK had known about.

The Panel noted that the hard copy of the email provided by the complainant differed from that provided by Daiichi-Sankyo. The complainant's copy finished at 'Kind Regards, Your Lixiana Team from Daiichi-Sankyo Europe' and stated 'RESTRICTED' in the bottom right-hand corner of the page. The email provided as part of the company's response included, *inter alia*, a short video of a named consultant embedded within it and the European prescribing information within the body of the email. The Panel further noted Daiichi-Sankyo's assertion that the materials submitted by the complainant were incomplete and misleading. The Panel noted that the complainant had, however, referred to both an email and video being sent to his/her patient.

The complainant stated that he/she had received two further emails and videos making a total of six promotional materials all with the same breaches. The latter statement appeared inconsistent with the complainant's initial comment that the original email in question had been sent to his/her patient. It was not clear to the Panel if the complainant's patient had also received the second and third emails. The complainant did not provide copies of the further two emails and videos, but these were provided as part of Daiichi-Sankyo's response. The complainant was anonymous and non-contactable and therefore the Panel could not contact him/her for further information.

The Panel based its rulings on the first email of the campaign, part of which was provided by the complainant, and the associated video provided by Daiichi-Sankyo, as well as the third video in the series in relation to the complainant's allegation regarding use of the claim 'ideal'.

The Panel noted Daiichi-Sankyo's submission that for the email campaign in question, Daiichi-Sankyo Europe instructed its agency to only target cardiologists and that the agency had a

process in place to ensure that those who signed up to access its website/join its database had declared themselves to be health professionals; an additional, explicit opt-in for receiving promotional emails was solicited, and such emails might only be sent to those health professionals who had opted in. The Panel noted the information that was requested by the agency upon registration including a medical licence number for UK health professionals and that this requirement was only provisionally removed after the email campaign in question.

The Panel noted Daiichi-Sankyo's submission that the agency had, during the course of a previous engagement with Bayer, manually added two Bayer employees to its database, at the employees' request, and that their details were mistakenly not removed after the project with Bayer had ended. The Panel, noted, however, that Bayer had contacted Daiichi-Sankyo on 2 September 2020 to complain about the email campaign which was immediately stopped the following day. It appeared that the matter had thus been dealt with under inter-company dialogue between Daiichi-Sankyo and Bayer. The Panel additionally noted that the complaint concerned receipt of the email in question by a specific patient, the complainant did not make a general direct or indirect allegation about the broader distribution of the email in question. Whilst the Panel was concerned about receipt of the email in question by two Bayer employees it decided on balance that that matter did not fall within the scope of the complaint and thus it would make no ruling about the matter.

The Panel noted that Clause 9.9 related to permission being obtained from a recipient prior to promoting via, *inter alia*, email and therefore was only relevant in relation to health professionals and other relevant decision makers. The Panel noted the complainant's statement that his/her patient (the recipient) had never agreed to receive such emails. The Panel further noted that the complainant had not provided any evidence about the professional status or otherwise of the patient and that he/she bore the burden of proof in this regard. In the Panel's view the complainant had not established on the balance of probabilities that the email in question, or the other two emails that he/she referred to receiving, had been received by a health professional without his/her prior permission; the complainant only referred to the first email being received by his/her patient without permission and thus Clause 9.9 did not apply to that allegation. The Panel therefore ruled no breach of Clause 9.9.

The Panel noted that Clause 11.3 stated, *inter alia*, that mailing lists must be kept up-to-date and requests to be removed from promotional mailing lists must be complied with promptly. In that regard, noting its comments above, the Panel did not consider that Clause 11.3 applied to the complainant's allegation regarding his/her patient and thus it ruled no breach of Clause 11.3.

Furthermore, the Panel noted Daiichi-Sankyo's submission that whilst both Bayer employees received the first email of the campaign, one subsequently opted out and did not receive the second and third emails; that demonstrated that the opt-out process functioned as intended.

The Panel noted that 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 Panel noted that the complainant bore the burden of proof and had not provided any evidence about the health professional status or otherwise of his/her patient such that one could determine whether the material was tailored to the audience. On the evidence available, the Panel ruled no breach of Clause 11.1.

The Panel noted Daiichi-Sankyo's submission that aside from the two Bayer employees, all of the database registrants and thereby recipients of the email campaign in question would have

provided medical licence numbers and declared themselves to be health professionals. The Panel noted that receipt of the email by two Bayer employees was covered by its decision above. The Panel also noted its comments above that the opt-out facility appeared to function as intended, and that the complainant had not provided any evidence about the health professional status or otherwise of his/her patient. The Panel noted that the complainant had not established, on the balance of probabilities, that members of the public had received the email in question and no breach of Clauses 26.1 and 26.2 were 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 Panel noted that the subject line of the email in question stated 'Lixiana Presents -The Evidence - Series 1 / Episode 1'. The Panel noted that 'Daiichi-Sankyo' was named as the sender of the email and the email domain was that of the third-party agency. The Panel further noted that the email was signed by 'Your Lixiana Team from Daiichi-Sankyo Europe'. As noted above, the materials provided by the complainant and the company differed; the email provided by the company appeared to be complete and so the Panel considered the allegation in relation to that email. The email provided by the company included the Lixiana European prescribing information and the Daiichi-Sankyo logo on the last page. In the Panel's view the complainant had not proved on the balance of probabilities that the email campaign was disguised promotion; it was sufficiently clear that the email was promotional material from Daiichi-Sankyo and the Panel therefore ruled no breach of Clauses 9.10 and 12.1.

The Panel noted that the promotional email intended for health professionals did not include Lixiana's non-proprietary name immediately adjacent to the brand name at its first appearance in the email subject line and a breach of Clause 4.3 was ruled. The Panel further noted that the email in question did not include the adverse events reporting statement as required by the Code and a breach of Clause 4.9 was ruled. Finally, the Panel noted that Clause 4.8 stated that promotional material other than advertisements appearing in professional publications must include the date on which the promotional material was drawn up or last revised. The Panel noted that that information was not included on the email at issue and a breach of Clause 4.8 was ruled. All of those rulings were as acknowledged by Daiichi-Sankyo.

With regard to the provision of prescribing information, Daiichi-Sankyo submitted that the copy of the email which it had provided to the Authority included the European prescribing information at the end of it. The Panel noted Daiichi-Sankyo's submission that the UK prescribing information differed slightly from the European version; Daiichi-Sankyo, however, did not provide any details of the differences although the Panel noted that the UK cost of the medicine was missing.

The Panel noted that Clause 4.2 listed the content of prescribing information which was required by Clause 4.1 to be provided with all promotional material. Failure to satisfy Clause 4.2 was therefore a breach of Clause 4.1. The Panel noted that Clause 4.4 required that in the case of digital material such as emails, the prescribing information as required by Clause 4.1 might be provided either by inclusion in the digital material itself, or by way of a clear and prominent direct single click link. Clause 4.5 stated that in the case of audio-visual material such as films, the prescribing information might be provided either by way of a document which was made available to all persons to whom the material was shown or sent or by inclusion on the audio-visual recording or in the interactive data system itself.

The Panel noted that whilst the European prescribing information was provided within the first email provided by Daiichi-Sankyo and at the end of the video associated with that email, it did not appear to include the UK cost of the medicine as required by Clause 4.2. The requirement to include prescribing information was therefore not met and breaches of Clauses 4.1 and 4.4 were ruled in relation to the email and breaches of Clauses 4.1 and 4.5 were ruled in relation to the video.

The Panel noted the complainant's allegation that the visual of a patient with multiple heads was inappropriate for patients, in breach of Clause 9.1. The Panel noted Daiichi-Sankyo's submission that the material in question was not targeted at patients and although the visual was designed to be arresting, it was selected based on market research conducted with health professionals ie an appropriate audience. The Panel did not consider that the complainant had established that use of the image in the promotional email meant that Daiichi-Sankyo had failed to maintain high standards. The Panel therefore ruled no breach of Clause 9.1.

The Panel noted that in the third video in the series titled 'Lixiana in challenging NVAF patients – Practical benefits' the speaker stated:

> 'With our most challenging patients, particularly and the use of edoxaban, there are a few patients where it's particularly helpful. I think where they are at risk of bleeding, particularly non-GI bleeds and particularly intercranial haemorrhage, I think edoxaban is ideal.'

In addition, during the presentation a box in the top left-hand side of the screen stated 'Edoxaban is ideal for elderly patients at risk of bleeding'. The Panel noted Daiichi-Sankyo's submission that it did not defend the use of the word 'ideal' in the video in question. The Panel further noted Daiichi-Sankyo's submission that use of 'the proven choice' as the title of the first video and within the email at issue and 'ideal' which appeared in the third video in the series was not in accordance with UK standards. The Panel noted that the email at issue referred to 'The Proven Choice' which in the Panel's view referred to Lixiana, and the opening screen of the video in that email clearly stated 'Lixiana-The Proven Choice'. The Panel noted Daiichi-Sankyo's submission that the claim of 'the proven choice' in the title of the first video and as stated in the email in question referred to the quantity and consistency of the clinical and real-world evidence available for edoxaban which had not been made sufficiently clear in the materials and might be interpreted to be an implicit comparison to other medicines and was therefore not capable of substantiation. The Panel therefore ruled breaches of Clauses 7.2, 7.3, 7.4 and 7.10 in relation to use of the claim 'the proven choice' in the first email and its video and use of 'ideal' in the claim in the third video of the series as acknowledged by Daiichi-Sankyo.

The Panel noted Daiichi-Sankyo's submission that the first video which was in the email in question referred to a Lixiana clinical trial which included a 'low dose' treatment arm, which was not in-label. Daiichi-Sankyo submitted that either it should have omitted the information or made it clear that that was not a licensed dose. The Panel ruled a breach of Clause 3.2 as acknowledged by the company.

The Panel noted Daiichi-Sankyo's submission that its European affiliate had not briefed it on the email campaign and had failed to get the campaign certified in accordance with the ABPI Code before it was launched and no certificate existed. The Panel therefore ruled a breach of Clause 14.1 as acknowledged by the company. The Panel noted that Clause 14.5 related primarily to the content of the certificate. The Panel also noted that whilst the complainant had cited Clause

14.5 the allegation referred to approval of the material rather than the content of the certificate. The Panel thus decided that Clause 14.5 was not applicable and ruled no breach of that Clause.

The Panel noted that the complainant had queried whether any contracts and payments to those UK doctors who had appeared in the video were approved and had alleged potential breaches of Clauses 23.1and 23.2 as well as Clauses 24.1 and 24.2 in relation to disclosure.

The Panel noted Daiichi-Sankyo's submission that the videos were originally made in 2018 at the ESC. The 2018 project was known to Daiichi-Sankyo UK and the contracts for both named health professionals involved were examined and approved by Daiichi-Sankyo UK; the contracts were signed at the ESC by representatives of Daiichi-Sankyo Europe as well as by the two consultants. The Panel did not have a copy of the contracts before it. The Panel noted that the complainant bore the burden of proof and had not provided evidence to show that the contracts with the consultants were in breach of Clause 23.1 as alleged and no breach was ruled.

The Panel noted Daiichi-Sankyo's submission that a review of it and Daiichi-Sankyo Europe's financial records, showed that despite multiple reminders, the health professionals had not yet submitted valid invoices for their services and had thus not been paid. The Panel noted there were thus no transfers of value to declare and therefore ruled no breach of Clauses 23.2, 24.1 and 24.2.

The Panel noted its comments and rulings of breaches of the Code above and considered that Daiichi-Sankyo had failed to maintain high standards in the conduct of the email campaign in question; the Panel therefore ruled a breach of Clause 9.1.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted that examples of activities likely to be in breach of this clause listed in the supplementary information included prejudicing patient safety. The Panel noted its rulings above, particularly the breaches of Clauses 4.9 and 3.2 and considered that Daiichi-Sankyo had reduced confidence in and brought discredit upon the industry; the Panel ruled a breach of Clause 2.

Complaint received **29 October 2020**

Case completed **1 April 2021**