CASE AUTH/3388/9/20

MEMBER OF THE PUBLIC v DAIICHI-SANKYO

Alleged promotion of Lixiana, Nilemdo and Nustendi to the public

An anonymous, contactable complainant who described him/herself as a member of the public complained about the promotion of Lixiana (edoxaban), Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) to the public by Daiichi-Sankyo UK. Lixiana was indicated for the treatment and prevention of certain thrombotic conditions and Nilemdo and Nustendi were both for use in certain adults with lipid or cholesterol disorders.

The complainant noted that a congress organised by a UK patient organisation, was about to take place. The public website listed the agendas of the live sessions and there was no signage to indicate it was for health professionals only. The complainant provided a web link to the congress programme.

The complainant noted that on 28 September there would be a 'Daiichi NN [congress] Live Symposia'. The agenda listed one session as 'The clinical challenges we face in dyslipidaemia'. The next session was 'Introducing Nilemdo and Nustendi', followed by 'Who is Nilemdo and/or Nustendi right for?'. The complainant submitted that this linked Nilemdo and Nustendi with the indication dyslipidaemia on a public website.

Similarly, the complainant noted that on 29 September the 'Daiichi Lixiana [congress] Live Symposia' with a session title of 'Tackling unmet need in NVAF' would take place; this linked Lixiana to the indication NVAF on a public website.

The complainant stated that there was no prescribing information, black triangle, adverse event reporting information, date of preparation or generic name for Nilemdo, Nustendi or Lixiana.

The complainant stated there was no declaration of the company's involvement for either symposia. That the symposia were listed on the 'live sessions' page suggested that they were part of the official congress agenda for the meeting, rather than company sponsored sessions.

The complainant alleged that high standards had not been maintained and that it had brought discredit on the industry.

The detailed response from Daiichi-Sankyo is given below.

The Panel considered the relationship between Daiichi-Sankyo and the patient organisation relevant to the complaint. The company sponsored both the patient organisation, as an organisation, and the congress, which was organised by it. Part of the congress sponsorship appeared to include two symposia. The Panel considered that the advertising of the pharmaceutical company symposia by the patient organisation was potentially covered by the Code and would be the responsibility of the pharmaceutical

company. It did not appear that the relationship between Daiichi-Sankyo and the patient organisation with regard to the two symposia and the exhibition stand was a strictly arm's length arrangement given that the symposia were Daiichi-Sankyo organised meetings, rather than sponsored by the company. The Panel was concerned that there were no clear instructions from Daiichi-Sankyo to the patient organisation about each party's role in relation to the symposia and the need to comply with the Code in promoting the symposia. It did not appear that Daiichi-Sankyo had provided the patient organisation with the wording for the symposia agenda to be used on the congress website. The statement of works provided appeared to be from the patient organisation to Daiichi-Sankyo.

The Panel noted that the weblink provided by the complainant was to the Live Sessions programme on the congress website. As listed on the programme for 2020 these included, '12:00 – 13:00 Daiichi NN [congress] Live Symposia Online – Monday 28 September' and '12:00-13:00 Daiichi Lixiana [congress] Live Symposia Online – Tuesday 29 September'. The agenda for each symposia appeared below on the same webpage. The Panel noted that the agenda made reference to Daiichi-Sankyo medicines, Lixiana, Nilemdo and Nustendi, and their associated therapeutic areas of use.

The Panel noted that it appeared that the complainant had accessed the Live Sessions programme directly from the congress website. The homepage of the website stated that the congress provided '…unrivalled opportunity for health care professionals interested in the management of arrhythmias to share effective practice, showcase innovation, learn about latest developments and network with UK & international delegates'. It was clear that the congress was aimed at health professionals. The Panel further noted Daiichi-Sankyo's submission that the congress and a link to the congress homepage was only listed on the health professional section of the patient organisation's website and therefore was not promoted to non-health professionals.

In the Panel's view, the congress website was aimed at health professionals and not aimed at the public and therefore it did not consider that the agenda for the two Daiichi-Sankyo symposia on the webpage in question, which appeared in the programme section of the website, promoted prescription only medicines to the public as alleged and no breaches of the Code were ruled.

With regard to the allegation in relation to the lack of prescribing information and other obligatory information on the webpage in question, the Panel disagreed with Daiichi-Sankyo's submission that the agenda on the webpage in question was not promotional. The Panel considered that the mention of Daiichi-Sankyo's medicines in association with their respective indications on the webpage at issue meant that the Code requirements applied. The Panel therefore ruled breaches of the Code for lack of prescribing information, omission of non-proprietary name immediately adjacent to the brand name at its first appearance, lack of a clear prominent statement as to where the prescribing information could be found, lack of a date on which the material was drawn up, lack of the adverse event reporting statement and omission of the inverted black triangles for each of Nilemdo, Nustendi and Lixiana, respectively, as alleged.

The Panel noted Daiichi-Sankyo's submission that it was a platinum sponsor of the congress and that the presentation of the agenda as displayed on the congress website was formatted and created by the patient organisation.

The Panel noted, however, that there was no sponsorship declaration on the webpage for readers to immediately understand the extent of the company's involvement and sponsorship of the entire meeting, rather than the Daiichi-Sankyo symposia. The contract with the patient organisation, as stated in the statement of work provided, made no reference to the requirement for a sponsorship statement in this regard. The Panel ruled a breach of the Code.

The Panel considered that its ruling of a breach of the Code in relation to the sponsorship of the meeting as a whole covered the matter in relation to the inadequate declaration of sponsorship and therefore the Panel ruled no breaches of the Code.

The Panel was concerned to note that Daiichi-Sankyo's contract with the patient organisation did not refer to the requirements of the Code in relation to declaration of sponsorship and it appeared to the Panel that Daiichi-Sankyo had not adequately briefed the organisers with regards to the requirements of the Code in relation to presentation of the company symposia agenda on the programme at issue. The Panel considered that Daiichi-Sankyo had failed to maintain high standards in this regard and a breach of the Code was ruled.

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

An anonymous, contactable complainant who described him/herself as a member of the public complained about the promotion of Lixiana (edoxaban), Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) to the public by Daiichi-Sankyo UK Limited. Lixiana was indicated for the treatment and prevention of certain thrombotic conditions and Nilemdo and Nustendi were both for use in certain adults with lipid or cholesterol disorders.

COMPLAINT

The complainant noted that a congress organised by a UK patient organisation, was about to take place. The public website listed the agendas of the live sessions and there was no signage to indicate it was for health professionals only. The complainant provided a web link to the congress programme.

The complainant noted that on 28 September there would be a 'Daiichi NN [congress] Live Symposia'. The agenda listed one session as 'The clinical challenges we face in dyslipidaemia'. The next session was 'Introducing Nilemdo and Nustendi', followed by 'Who is Nilemdo and/or Nustendi right for?'. The complainant submitted that this linked Nilemdo and Nustendi with the indication dyslipidaemia on a public website and in that regard referred to Clauses 26.1 and 28.1.

Similarly, the complainant noted that on 29 September the 'Daiichi Lixiana [congress] Live Symposia' with a session title of 'Tackling unmet need in NVAF' would take place; this linked Lixiana to the indication NVAF on a public website. Again, the complainant cited Clauses 26.1 and 28.1.

The complainant stated that there was no prescribing information (Clauses 4.1 and 4.6) or black triangle (Clause 4.10) or adverse event reporting information (Clause 4.9), date of preparation (Clause 4.8) or generic name (Clause 4.3) for Nilemdo, Nustendi or Lixiana.

The complainant stated there was no declaration of the company's involvement for either symposia (Clauses 22.4, 27.2 and 27.9). That the symposia were listed on the 'live sessions' page suggested that they were part of the official congress agenda for the meeting, rather than company sponsored sessions.

The complainant alleged that high standards had not been maintained (Clause 9.1) and that it had brought discredit on the industry (Clause 2).

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 4.1, 4.3, 4.6, 4.8, 4.9, 4.10, 9.1, 22.4, 26.1, 27.2, 27.9 and 28.1 of the Code.

RESPONSE

By way of background with regard to the patient organisation, Daiichi-Sankyo referred to the following text from the patient organisation's website:

> '[The patient organisation] is a coalition of charities, patient groups, patients, carers, medical groups and allied professionals. Although these groups remain independent, they work together under the [patient organisation] umbrella to promote timely and effective diagnosis and treatment of arrhythmias.'

The website listed the organisation's core aims and objectives and in that regard noted that the patient organisation might be seen as a patient organisation (as described by the complainant); or a medical association; or a mix of both. Other patient organisations had a dual purpose of championing a patient perspective whilst improving patient care through enhancing the skills and knowledge of health professionals.

Daiichi-Sankyo stated that a screenshot of the patient organisation's website (taken 3 October 2020) clearly showed it recognised that its two primary target audiences had distinct needs and had appropriate programmes for each, including having programmes listed on separate areas on its website.

Screenshots (again taken on October 3) showed that the congress was only listed on the health professional section of the site and was not promoted to non-health professionals.

Daiichi-Sankyo submitted that its contract with the patient organisation, as stated in the statement of work (copy provided), clearly indicated in the objectives section that the company would provide 'educational and promotional content for health care professionals with an interest in cardiovascular disease for brands belonging to Daiichi-Sankyo'.

Daiichi-Sankyo noted that the complainant had drawn attention to the congress and made several allegations regarding the appropriateness of the content for the public and for health professionals. Daiichi-Sankyo denied all alleged breaches of the Code.

<u>The congress</u>

Daiichi-Sankyo noted that the link to the conference homepage was only available from the health professional section of the patient organisation website. Two screenshots (provided) of the landing page clearly indicated the intended target audience comprised health professionals.

The breadcrumb format of the navigation [Home > For Clinicians > […Congress] shown in a blue banner at the top of the page indicated the information was available from the health professional section of the website and the accompanying headline claim declared 'News and Information for Arrhythmia Clinicians'. The opening line of text declared: '[Congress] provides unrivalled opportunity for health care professionals interested in the management of arrhythmias to share effective practice, showcase innovation, learn about latest developments and network with UK & international delegates'. The penultimate bullet point referred to the application for continuing professional development (CPD) to the Royal College of Physicians. The foot of the website page referred to the 2019 conference and stated 'Heart rhythm experts from across the world met at the 14th Annual Congress – the UK's biggest arrhythmia specialist event'. The papers and abstracts from the event were hosted by a named medical publisher).

Daiichi-Sankyo submitted that the congress was clearly intended and labelled as a health professional event. The 2020 conference took place on 27-30 September and when the screenshots were taken (3 October 2020), the patient organisation and conference websites had not been updated post-conference.

Daiichi-Sankyo provided a web link to the main conference website.

A screenshot of the conference landing page (taken 3 October) was provided (the text appeared beneath a video montage of last year's conference). The first line of text referred to the target audience: '[Congress] provides unrivalled opportunity for health care professionals interested in the management of arrhythmias to share effective practice, showcase innovation, learn about latest developments and network with UK & international delegates'. This was a typical conference website and was not dissimilar from those of any health professional conference organiser.

Daiichi-Sankyo noted that a separate virtual patient's event was planned for 2020; this, again, clearly showed the intent to maintain the health professional and non-health professional audiences and was advertised from the patient organisation patient website (Daiichi-Sankyo referred to the screenshots provided).

Daiichi-Sankyo stated that it was a proud sponsor of the patient organisation and was a platinum sponsor of its congress for health professionals on 27-30 September 2020. Daiichi-Sankyo held two live events which were clearly indicated as company sponsored symposia. Daiichi-Sankyo also provided internally approved materials for the virtual exhibition space. Daiichi-Sankyo submitted it had no input into the creation of the conference or any of the materials created by the patient organisation to advertise it, including the website. Accordingly, Daiichi-Sankyo did not certify any of the organiser's materials.

The patient organisation had confirmed that the event organisation was independent of Daiichi-Sankyo. The email stated that the congress website was owned, and all content and updates were managed, by the patient organisation directly. In addition, the patient organisation stated that all other content provided by Daiichi-Sankyo for its exhibition stand was hosted on a password protected website only accessible by health professionals and exhibitors with a double layer of protection.

Daiichi-Sankyo submitted that it did not approve, or have the opportunity to influence, the content of the webpages at issue and it provided separate email confirmation from the patient organisation that it had acted unilaterally and without any involvement from Daiichi-Sankyo.

In addition, the agency that Daiichi-Sankyo commissioned to support the company in its collaboration with the patient organisation provided an email where the patient organisation previously acknowledged that it would not use any of Daiichi-Sankyo's content on its external facing website (copy provided).

Allegations regarding promotion to the public

Daiichi-Sankyo stated that the conference, conference website and materials were created and operated independently from Daiichi-Sankyo. The conference website was typical of that created by medical associations in respect of their medical congresses. The target audience was clearly stated. Content related to Daiichi-Sankyo was not visible from the homepage. No medicines were mentioned on the homepage.

Daiichi-Sankyo stated that it was true that the details of the agenda were visible to those that were seeking the information. On the tab 'Industry sessions', was a list of webinar-style content run by different companies, including Daiichi-Sankyo (screenshot provided). It was also possible to download a copy of the complete agenda. As such, the information pertaining to product was several layers inside a website that was clearly labelled as being targeted at health professionals.

Daiichi-Sankyo stated that in response to this complaint, the patient organisation had removed details of the Daiichi-Sankyo webinar from the website, however a screenshot of how it originally appeared was provided. For clarity, this version of the conference agenda was created by the patient organisation, completely independently, and without Daiichi-Sankyo's knowledge or agreement. There were two Daiichi-Sankyo webinars: 12-1pm on Monday, 28 September; and 12-1pm on Tuesday, 29 September. On the version of the agenda displayed on the conference website, one product name was visible, however, Daiichi-Sankyo submitted that this was entirely appropriate so as to provide clarity about the session content; and was entirely appropriate for the intended health professional audience. However, Daiichi-Sankyo submitted that it did not create the webpage or contribute to its creation and in that regard, noted that the company name was shortened to 'Daiichi', and also abbreviated the company's brand names Nilemdo and Nustendi to 'NN' which Daiichi-Sankyo would never do.

Daiichi-Sankyo stated that the full conference programme was also created by the patient organisation without any input from Daiichi-Sankyo. Although Daiichi-Sankyo set the agenda for its own webinars and certified the Daiichi-Sankyo advertisements for the webinars accordingly, the exact presentation of all the industry webinar agendas as displayed in the conference programme was formatted and created by the patient organisation without any input, knowledge or agreement from Daiichi-Sankyo.

Daiichi-Sankyo provided the full programme booklet and screenshots of the elements pertinent to Daiichi-Sankyo.

Daiichi-Sankyo recognised that the webinar agenda named its products, but this was to provide clarity about the content and was entirely appropriate for the intended health professional audience. Daiichi-Sankyo reiterated that the agenda was produced solely by the patient organisation without the knowledge, input or agreement from Daiichi-Sankyo.

Daiichi-Sankyo stated that there was no promotion of medicines to the general public and it denied any breach of Clause 26.1.

Daiichi-Sankyo submitted that the website was clearly targeted at health professionals and was operated independently from the company; it was not intended for viewing by the general public. The promotional content intended for health professionals was not immediately accessible from the homepages and was clearly signposted. It could only be accessed after completing a registration process and logging into the website. The Daiichi-Sankyo webinar sessions would only be available on the day, after having logged into the website. Therefore, the content of these sessions was not accessible to the general public.

As a healthcare organisation website that was clearly targeted at health professionals, the website in question did not require access restrictions as covered in Clause 28.1. Regardless of that fact, a gateway did exist. For both reasons, Daiichi-Sankyo denied a breach of Clause 28.1.

Daiichi-Sankyo noted the complainant's concern that the company's involvement in the sessions was not clearly represented, noting that the sessions were on the 'live' section, rather than the 'industry' section of the programme. As could be seen from screenshots provided, the programme was clearly labelled with all the company names, including the reference on both webinars to 'Daiichi'. The 'live' element simply referred to the event being broadcast as it was happening, rather than being pre-recorded. Independent content was included (in the usual manner) in the 'Plenary' section. Daiichi-Sankyo categorically denied a breach of Clause 22.4.

In this regard (transparency of involvement), the complainant also alleged breaches of Clauses 27.2 and 27.9. Whilst Daiichi-Sankyo recognised that the patient organisation was partly a patient organisation and partly a medical society, in this context, the conference activities should be regarded as interactions with a healthcare organisation rather than a patient organisation. Regardless, the 'Daiichi' element of Daiichi-Sankyo's company name was clearly represented on the programme and those who read the programme or visited to the conference would be in no doubt as to the nature of Daiichi-Sankyo's involvement. Daiichi-Sankyo denied breaches of Clauses 27.2 and 27.9.

Daiichi-Sankyo noted that the complainant had raised concerns about the lack of mandatory information on the health professional-facing documents. Daiichi-Sankyo again reiterated that it was not involved in the creation of those conference programme documents. All material created by Daiichi-Sankyo was appropriately certified and contained appropriate mandatory information. The fact that the conference programme created by the conference organiser named Daiichi-Sankyo products was not within the company's control; nor would Daiichi-Sankyo regard the overall conference agenda as promotional material. Accordingly, Daiichi-Sankyo denied breaches of Clauses 4.1, 4.3, 4.6, 4.8 and 4.10.

Daiichi-Sankyo stated that it was proud of its sponsorship of the congress and the patient organisation. The company submitted that it had acted appropriately and had certified all its material in accordance with the Code. The elements of the conference documents referred to by the complainant were not within Daiichi-Sankyo's control and were not atypical of those created by all conference organisers at all scientific congresses.

Daiichi-Sankyo categorically denied breaches of Clauses 9.1 and 2. Daiichi-Sankyo considered that it had aspired to the high standards rightly expected by the Code and that it had acted entirely appropriately in this instance.

PANEL RULING

The Panel considered the relationship between Daiichi-Sankyo and the patient organisation relevant to the complaint. The company sponsored both the patient organisation, as an organisation, and the Congress, which was organised by the patient organisation. Part of the congress sponsorship appeared to include two symposia. The Panel considered that the advertising of the pharmaceutical company symposia by the patient organisation was potentially covered by the Code and would be the responsibility of the pharmaceutical company. It did not appear that the relationship between Daiichi-Sankyo and the patient organisation with regard to the two symposia and the exhibition stand was a strictly arm's length arrangement given that the symposia were Daiichi-Sankyo organised meetings, rather than sponsored by the company. The Panel was concerned that there were no clear instructions from Daiichi-Sankyo to the patient organisation about each party's role in relation to the symposia and the need to comply with the Code in promoting the symposia. It did not appear that Daiichi-Sankyo had provided the patient organisation with the wording for the symposia agenda to be used on the Congress website. The statement of works provided appeared to be from the patient organisation to Daiichi-Sankyo.

The email to Daiichi-Sankyo from the patient organisation (dated 29 September 2020) stated that the patient organisation was unaware of the need to obtain approval from Daiichi-Sankyo to include the symposia on the Congress website. The email also stated that once the patient organisation was made aware of the situation, it was removed from the website. The Panel noted Daiichi-Sankyo's submission that it had provided the patient organisation with certified materials for the company's exhibition stand including materials promoting the company's symposia on a password protected separate website which was only accessible to health professionals and exhibitors and which included a link to prescribing information.

The Panel noted that the weblink provided by the complainant was to the Live Sessions programme on the Congress website. As listed on the programme for 2020 these included, '12:00 – 13:00 Daiichi NN [congress] Live Symposia Online – Monday 28 September' and '12:00-13:00 Daiichi Lixiana [congress] Live Symposia Online – Tuesday 29 September'. The agenda for each symposia appeared below on the same webpage. The Panel noted that the agenda made reference to Daiichi-Sankyo medicines, Lixiana, Nilemdo and Nustendi, and their associated therapeutic areas of use.

The Panel noted that it appeared that the complainant had accessed the Live Sessions programme directly from the HRC website. The homepage of the website stated that the congress provided '…unrivalled opportunity for health care professionals interested in the management of arrhythmias to share effective practice, showcase innovation, learn about latest developments and network with UK & international delegates'. It was clear that the congress was aimed at health professionals. The Panel further noted Daiichi-Sankyo's submission that the congress and a link to the congress homepage was only listed on the health professional section of the patient organisation website and therefore was not promoted to non-health professionals.

In the Panel's view, the congress website was aimed at health professionals and not aimed at the public and therefore it did not consider that the agenda for the two Daiichi-Sankyo symposia

on the webpage in question, which appeared in the programme section of the website, promoted prescription only medicines to the public as alleged and no breach of Clause 26.1 was ruled.

With regard to the complainant's reference to Clause 28.1 in relation to the alleged promotion of prescription only medicines to the public, given its ruling of no breach of Clause 26.1, the Panel also ruled no breach of Clause 28.1.

With regard to the allegation in relation to the lack of prescribing information and other obligatory information on the webpage in question, the Panel disagreed with Daiichi-Sankyo's submission that the agenda on the webpage in question was not promotional. The 28 September Daiichi-Sankyo symposium agenda clearly associated Nilemdo and Nustendi with the treatment of dislipidaemia and the 29 September Daiichi-Sankyo symposium agenda associated Lixiana with use in NVAF [nonvalvular atrial fibrillation]. The Panel considered that Daiichi-Sankyo was responsible for ensuring that material used to promote its company symposia (including the official conference programme) complied with the Code. In this regard, the Panel considered that the mention of Daiichi-Sankyo's medicines in association with their respective indications on the webpage at issue meant that the Code requirements in relation to Clause 4 applied. The Panel therefore ruled a breach of Clauses 4.1, 4.3, 4.6, 4.8, 4.9 and 4.10 for lack of prescribing information, omission of non-proprietary name immediately adjacent to the brand name at its first appearance, lack of a clear prominent statement as to where the prescribing information could be found, lack of a date on which the material was drawn up, lack of the adverse event reporting statement and omission of the inverted black triangles for each of Nilemdo, Nustendi and Lixiana, respectively, as alleged.

The Panel noted that near the bottom of the webpage it stated that the congress was organised by the patient organisation. The Panel noted Daiichi-Sankyo's submission that it was a platinum sponsor of the congress and that the presentation of the agenda as displayed on the HRC website was formatted and created by the patient organisation.

The Panel noted that 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 were aware of it at the outset.

The Panel noted the complainant's concern that the two Daiichi-Sankyo symposia were listed on the 'live sessions' page which suggested that they were part of the official congress agenda rather than company sponsored sessions. The Panel noted Daiichi-Sankyo's submission that the 'live' element simply referred to the event being broadcast as it was happening, rather than being pre-recorded. Independent content was included in the 'Plenary' section. Whilst the Panel queried why the Daiichi-Sankyo symposia were not included in both the list of live and industry sessions, it noted that the programme and symposia agenda on the webpage at issue referred to the symposia as 'Daiichi' symposia, and health professionals attending the event would, on the balance of probabilities, know Daiichi was a pharmaceutical company, and would be aware that the two symposia were organised by Daiichi-Sankyo. The two symposia were within the full control of the company and were not sponsored as such.

The Panel noted, however, that there was no sponsorship declaration on the webpage for readers to immediately understand the extent of the company's involvement and sponsorship of the entire meeting, rather than the Daiichi-Sankyo symposia. The contract with the patient

organisation, as stated in the statement of work provided, made no reference to the requirement for a sponsorship statement in this regard. The Panel ruled a breach of Clause 22.4.

The complainant referred to the patient organisation and raised Clauses 27.2 and 27.9 which covered requirements when working with such organisations. The Panel noted Daiichi-Sankyo's submission that the patient organisation might be seen as either a patient organisation or a medical association or a mix of both and that the patient organisation website had a section for health professionals and a separate section for patients. The Panel further noted Daiichi-Sankyo's submission that a link to the congress from the patient organisation's website homepage was only available from the health professional section. The Panel noted that the conference activities were regarded by Daiichi-Sankyo as interactions with a healthcare organisation rather than a patient organisation. The Panel accepted that there were some organisations which were difficult to categorise as either healthcare organisations or patient organisations and it was for companies to decide. It would be helpful if the position was made clear in a company's standard operating procedures (SOPs) and its methodological note for disclosing transfers of value. It appeared that the payment was for a meeting held in 2020 so disclosure of the transfer of value would not be required until 30 June 2021.

The Panel considered that its ruling of a breach of Clause 22.4 in relation to the sponsorship of the meeting as a whole covered the matter in relation to the inadequate declaration of sponsorship and therefore the Panel ruled no breach of Clauses 27.2 and 27.9.

The Panel was concerned to note that Daiichi-Sankyo's contract with the patient organisation did not refer to the requirements of the Code in relation to declaration of sponsorship and it appeared to the Panel that Daiichi-Sankyo had not adequately briefed the organisers with regards to the requirements of the Code in relation to presentation of the company symposia agenda on the programme at issue. The Panel considered that Daiichi-Sankyo had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

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

APPEAL BY THE COMPLAINANT

The complainant accepted the Panel's rulings of no breach of Clauses 26.1, 27.2, 27.9 and 28.1 but appealed the ruling of no breach of Clause 2. The complainant stated that his/her reason for this appeal was the number of areas of concern that had been identified regarding the company's interactions with third parties and the lack of understanding of required processes at the company. The complainant referred to the Panel's ruling in which it stated that it was concerned that there were no clear instructions from Daiichi-Sankyo to the patient organisation about each party's role in relation to the symposia and the need to comply with the Code in promoting the symposia. The Panel was also concerned that Daiichi-Sankyo's contract with the patient organisation did not refer to the requirements of the Code in relation to the declaration of sponsorship and it appeared to the Panel that Daiichi-Sankyo had not adequately briefed the organisers with regard to the requirements of the Code in relation to presentation of the company symposia agenda on the programme at issue. The complainant alleged that if the company did not brief or instruct third parties in its contracts and agreements about the need to comply with the Code, or even refer to what those requirements were, this in itself was sufficient to bring discredit upon, or reduce confidence in, the industry which would be a breach of Clause 2.

COMMENTS FROM DAIICHI-SANKYO

On notification that the complainant had appealed the Panel's ruling of no breach of Clause 2, but prior to receiving the reasons for appeal, Daiichi-Sankyo provided the following response.

Daiichi-Sankyo submitted that the Panel had made the correct rulings for the following reasons:

- With regret high standards were not maintained as Daiichi-Sankyo had not adequately briefed the organisers with regard to the requirements of the Code in relation to presentation of the company symposia agenda on the programme at issue. Daiichi-Sankyo submitted that had it acted accordingly the organisers would not have acted unilaterally and placed an authorised version of the official symposium agenda on the public facing part of its website. A breach of Clause 9.1 was ruled.

- Having accepted responsibility for the acts of the third party, Daiichi-Sankyo recognised that the organisers act of unilaterally placing an authorised version of the official symposium agenda on the public facing part of its website brought the material under the Code for the following breaches:

    - Lack of prescribing information, omission of non-proprietary name immediately adjacent to the brand name at its first appearance, lack of a clear prominent statement as to where the prescribing information could be found, lack of a date on which the material was drawn up, lack of the adverse event reporting statement and omission of the inverted black triangles for each of Nilemdo, Nustendi and Lixiana, respectively. Breaches of Clauses 4.1, 4.3, 4.6, 4.8, 4.9 and 4.10 were ruled.

    - Lack of sponsorship declaration on the webpage for readers to immediately understand the extent of the company's involvement and sponsorship of the entire meeting, rather than the Daiichi-Sankyo symposia. The contract with the [patient organisation], as stated in the statement of work made no reference to the requirement for a sponsorship statement in this regard. A breach of Clause 22.4 was ruled.

    The Panel also ruled that the circumstances of this case did not warrant a ruling of a breach of Clause 2, which 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 breach of Clause 2.

For clarity, Daiichi-Sankyo submitted, based on the circumstances of this case, the Panel made the correct rulings, including the decision not to rule a breach of Clause 2.

On receipt of the complainant's reasons for appeal, Daiichi-Sankyo submitted that it had no further comment to add. Daiichi-Sankyo's rationale in support of the PMCPA's original ruling was set out above.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant was provided with both of Daiichi-Sankyo's responses, and he/she had no final comments.

APPEAL BOARD RULING

The Appeal Board was concerned to note that Daiichi-Sankyo had not adequately briefed the patient organisation on the requirements of the Code. These failings had led to the Panel's rulings of breaches of the Code (Clauses 4.1, 4.3, 4.6, 4.8, 4.9, 4.10 and 22.4) as well as a breach of Clause 9.1 for its failure to maintain high standards. These rulings were not appealed.

The Appeal Board noted that Clause 2 was a sign of particular censure and reserved for that use. The Appeal Board did not consider that in the circumstances of this case a breach of Clause 2 was warranted. In the Appeal Board's view, the complainant's broad 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 **24 September 2020**

Case completed **22 April 2021**