

HEALTH PROFESSIONAL v DAIICHI SANKYO

Allegations about a disease awareness campaign and an abbreviated advertisement for Nilemdo and Nustendi

A complainant who described him/herself as a health professional complained about Daiichi-Sankyo UK Ltd's relationship with a named patient organisation in relation to a disease awareness programme and separately about an abbreviated advertisement for Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) produced by Daiichi-Sankyo.

The complainant was concerned about a programme entitled 'Get clued-up on cholesterol' which was allegedly funded and influenced by Daiichi-Sankyo and carried out by the named patient organisation. The statement 'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign' appeared on the named patient organisation's website. The complainant alleged that the statement was missing on other website pages related to this programme.

The complainant was concerned that this was not an arm's length arrangement in that Daiichi-Sankyo identified areas of the country where people were living with high levels of cholesterol for the named patient organisation to reach out to and therefore in the complainant's view all material related to this programme required certification due to this being disease awareness and Daiichi-Sankyo's involvement.

The complainant stated that the patient organisation should have been instructed that the details of Daiichi-Sankyo's involvement needed to be provided from the outset in all communications about the programme.

The complainant further alleged that there was mention of Daiichi-Sankyo's product (bempedoic acid) on the treatments section which he/she considered was inappropriate for the public in the context of a disease awareness campaign as specific treatments were being advised.

The complainant also alleged that an abbreviated advertisement (BEM/21/0227, April 2021) for Nilemdo and Nustendi in the MIMS journal breached the Code as it contained three claims.

The detailed response from Daiichi Sankyo is given below.

The Panel considered that it was important that companies were clear about the classification of activities under the Code and that the classification should be

consistently described across materials including contracts. It appeared to the Panel that Daiichi-Sankyo had not distinguished between a contracted service provided by the named patient organisation to Daiichi-Sankyo versus sponsorship of that patient organisation's material and the company had used both terms within the statement of work (SOW) in relation to the disease awareness campaign. The term sponsorship was used in the SOW solely in relation to the Code requirement to declare details of a company's involvement in certain materials. The Panel noted that in its response to the complaint, Daiichi-Sankyo consistently described the relationship as sponsorship. The master services agreement (MSA) consistently described the arrangement between Daiichi-Sankyo and the named patient organisation as a contract for services save in one instance described above where the arrangements were described as a collaboration. A contracted service had different requirements under the Code to that of sponsorship of patient organisation material. Importantly, a pharmaceutical company contracting a patient organisation to provide it with a service would mean that the pharmaceutical company was responsible for the activity and materials under the Code. Whether a pharmaceutical company was responsible for materials produced as a result of a sponsorship would depend on the sponsorship arrangements.

The Panel noted that companies could sponsor patient organisation material and not be responsible for its content but only if the sponsorship was arm's length. The Panel noted Daiichi-Sankyo's submission that on the patient organisation's request, Daiichi-Sankyo shared the heatmaps with them and the patient organisation shared with Daiichi-Sankyo data analytics generated from the digital campaign which according to Daiichi-Sankyo meant that the interaction was a sponsorship. It appeared to the Panel, and acknowledged by Daiichi-Sankyo, that the arrangement was not arm's length and therefore, in the Panel's view, Daiichi-Sankyo was responsible for the content irrespective of whether the activity was classified as sponsorship of patient organisation material or the provision of contracted services.

The MSA referred to ownership of materials remaining with the named patient organisation which in the Panel's view appeared to be inconsistent with a contract for services. The SOW was not sufficiently clear about the classification of the materials. In the absence of a clear and unambiguous classification in the MSA and SOW, and noting the ownership of materials by the patient organisation and Daiichi-Sankyo's response on this point, the Panel considered, on balance, that the arrangements were a sponsorship which was not at arm's length and thus Daiichi-Sankyo was responsible for the content of the materials. Thus, the Panel made its rulings on that basis.

The Panel noted that the MSA and SOW were certified in September 2020, after the date of the commencement of services (14 July 2020) referred to in the SOW and considered that the contract had not been certified when the activity in question had commenced. The Panel therefore ruled a breach of the Code.

The Panel noted the content of the webpage accessed by the case preparation manager from the link provided by the complainant. The Panel queried Daiichi-Sankyo's submission that the 'landing page' was not accessible once the campaign had ended; the webpage in question had been accessed by the Case Preparation Manager in December 2021. This webpage was headed 'Get Clued-Up on Cholesterol' and immediately beneath stated 'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are

living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign'.

The Panel noted the complainant's allegation that the declaration of Daiichi-Sankyo's involvement in the campaign was missing from other webpages related to the campaign; the complainant did not identify any specific webpages. Daiichi-Sankyo submitted that the 'Let's get clued up on cholesterol' landing page was created specifically for the campaign and was a standalone piece and separate to the named patient organisation's official website, and that the 'Get Clued up on Cholesterol' questionnaire could only be accessed via the landing page which had the Daiichi-Sankyo disclaimer. The Panel did not have a copy of the questionnaire and did not know if it could be downloaded as a standalone item. Nor did it have copies of what were referred to in the SOW as 'downloadable heart healthy recipes'. The landing page had a section titled 'Tasty ways to manage your cholesterol' and it appeared to the Panel that these recipes were likely to be what was referred to in the SOW and the subject of the complainant's allegation. The Panel considered that if the recipes or the questionnaire were downloadable and/or could be directly accessed by any other route other than the landing page, a declaration of involvement would be required on each piece of material; however, according to Daiichi-Sankyo, its declaration of involvement was only on the landing page. The SOW stated that the recipes were downloadable and therefore, on the balance of probabilities, the Panel considered that there was downloadable material and the requirements for the declaration of sponsorship had not been met in relation to the downloadable recipes. A breach of the Code was ruled.

In relation to the complainant's reference to social media campaigns, Daiichi-Sankyo submitted that there was no reference to Daiichi-Sankyo on Facebook posts and users would have to click on the messages to go to a webpage which had reference to Daiichi-Sankyo's involvement. The Panel therefore ruled a further breach of the Code.

The Panel noted its decision above that the arrangement was one of sponsorship and as it was not an arm's length sponsorship, Daiichi-Sankyo was responsible for the materials. The Panel considered that all the educational material for the public required certification. Daiichi-Sankyo submitted that apart from the written agreements, no other materials or content relating to the campaign were certified by Daiichi-Sankyo. The Panel therefore ruled a breach of the Code.

In relation to the allegation that the written agreement was not clear on the requirement for a declaration of involvement from the outset for all parts of the programme, the Panel noted that the SOW stated that the patient organisation must always declare and acknowledge sponsorship from the outset. Whilst the Panel had concerns about the SOW in general as referred to above, the Panel noted that the complainant had cited the clause which referred to donations and grants. The Panel considered that the payment to the patient organisation did not constitute a donation or grant and therefore the clause raised was not relevant. No breach of the Code was ruled in that regard.

In relation to the allegation that bempedoic acid was referred to on the treatments page, the Panel noted Daiichi-Sankyo's submission that the treatment section on the patient organisation's website included all of the available lipid lowering treatments; at that time,

bempedoic acid and other new treatments were mentioned but not detailed on the website since they were not available.

Whilst the Panel considered that Daiichi-Sankyo was responsible for the content of the disease awareness programme, it was not responsible for the entire patient organisation's website which covered a number of topics. Nonetheless, the disease awareness material was hosted on the patient organisation's website and there appeared to be a link to the treatments page from the disease awareness page. The Panel noted that the Code did not prohibit disease awareness material referring to medicines. However, the relevant supplementary information stated that restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. In this regard, the Panel noted Daiichi-Sankyo's submission that the page in question included all lipid lowering treatments available at the time of the campaign. The Panel noted that the page referred to a range of medicines by different companies. The Panel noted that reference to a company's medicine in disease awareness material was not in itself necessarily a breach of the Code and thus based on the very narrow allegation, that the material referred to bempedoic acid, the Panel ruled no breaches of the Code. In any event, the Panel considered that the complainant had not established on the balance of probabilities that Daiichi-Sankyo was responsible for the treatments page in question.

The Panel was concerned about the failure to correctly and consistently classify the activity in the MSA and SOW and that Daiichi-Sankyo had not considered that it was responsible for the disease awareness materials given its acknowledgement that the arrangements were a sponsorship that was not at arm's length. Furthermore, the declaration of the company's involvement in the campaign was not on the Facebook posts, which were part of the written agreement. High standards had not been maintained in this regard and a breach of the Code was ruled.

Whilst the Panel had concerns about the relationship between Daiichi-Sankyo and the named patient organisation, noting the limited material provided by the complainant and the content of such material, on balance, it did not consider that the complainant had established that Daiichi-Sankyo had brought discredit upon the industry and no breach of Clause 2 of the Code was ruled.

In relation to the allegation about the abbreviated advertisement in MIMS journal, the Panel noted that the content of an abbreviated advertisement was restricted as set in the Code. Abbreviated advertisements may contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine was recommended for the indication or indications given.

The Panel noted that the advertisement in question was headed 'In the struggle against elevated LDL-C, add on to bring down'. Beneath an image of a clinician and a patient there was a second claim which stated, 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily Nilemdo or Nustendi'. Beneath the product logos was a third claim 'add on to take back control'. The Panel considered that the requirements of an abbreviated advertisement had not been met and ruled a breach of the Code as acknowledged by Daiichi-Sankyo. High standards had not been maintained in this regard and a breach of the Code was ruled.

A complainant who described him/herself as a health professional complained about Daiichi-Sankyo UK Ltd's relationship with a named patient organisation and separately about an abbreviated advertisement for Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe).

COMPLAINT

The complainant was concerned about a programme entitled 'Get clued-up on cholesterol' which was allegedly funded and influenced by Daiichi-Sankyo and carried out by a named patient organisation. On the patient organisation's website where this campaign was promoted, it was mentioned that 'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign'. The complainant provided a link to the website where the disclaimer was and submitted that this declaration was missing on the other website pages related to this programme. The complainant stated that each page was an individual entity related to this campaign and in the complainant's view the declaration of the company involvement should have been made aware from the outset on all pages related to this campaign as a member of the public could access a specific part of the website.

The complainant was concerned that this was not an arm's length arrangement in that Daiichi-Sankyo identified areas of the country where people were living with high levels of cholesterol for the named patient organisation to reach out to and therefore in the complainant's view all material related to this programme required approval as certification due to this being disease awareness and influence of content provision from Daiichi-Sankyo.

The complainant stated that the patient organisation should have been instructed that in both written and verbal communication about all parts of this programme to members of the public (eg when reaching out directly, social media campaigns) full involvement of Daiichi-Sankyo was provided from the outset but alleged that this was not the case. The complainant alleged that the grant written agreement could not have been clear on requiring declaration of involvement from the outset for all parts of the programme but even so in the complainant's view this was not a grant as it was not an arm's length arrangement as there had been company influence.

The complainant further stated that there was mention of Daiichi-Sankyo's product (bempedoic acid) on the treatments section which was inappropriate for viewing by members of the public in the context of a disease awareness campaign as specific treatments were being advised.

The complainant alleged that there had been breaches of Clauses 5.1, 5.5, 8.3, 23.2, 26.1, 26.2 and 2.

The complainant separately alleged that an abbreviated advertisement (BEM/21/0227, April 2021) for Nilemdo and Nustendi in the MIMS journal breached the Code; there were three claims on this advertisement but only one concise statement on such advertisements was allowed. Breaches of Clauses 13.8 and 5.1 were alleged.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 5.5, 8.3, 23.2, 26.1 and 26.2 of the 2021 Code in relation to the relationship with the

named patient organisation and its website and Clause 5.1 and 13.8 in relation to the MIMS advertisement.

RESPONSE

Daiichi-Sankyo submitted that it took its obligations under the ABPI Code seriously, strove to maintain high standards and to behave responsibly and ethically at all times.

Daiichi-Sankyo submitted that its relationship with the named patient organisation was open, transparent and non-promotional in nature with no intention to influence the independence of the patient organisation in anyway. This relationship included sponsorship of disease awareness campaigns, educational programmes and other non-promotional policy activities.

The company's involvement in the 'Get clued up on cholesterol' campaign involved providing funding to cover digital expertise and social media costs relating to the campaign. Daiichi-Sankyo was also involved in sharing information with the patient organisation, at its request, on data related to cardiovascular disease (CVD) burden and lipid hotspots areas across the UK, ie, the Daiichi-Sankyo UK heat maps. All this information was in the public domain and non-promotional in nature.

Following the campaign, the patient organisation shared with Daiichi-Sankyo Facebook's data analytics based on the target audience characteristics used to measure the success of the programme.

In addition, the responsibility of the relationship with the named patient organisation sat with the medical department only and there was no link to any commercial activities.

Allegation 1

Daiichi-Sankyo submitted that the 'Get Clued-up on Cholesterol' communications programme was the named patient organisation's cholesterol month disease awareness campaign using Facebook. As per the Statement of Work (SOW), the objective of the campaign was to reach one million people to talk about cholesterol during national cholesterol month in October 2020. This involved the named patient organisation creating a landing page, educational questionnaire, downloadable healthy recipes and identifying high risk CVD areas for people at risk. The campaign was officially launched by the patient organisation on 1 October 2020 and ended at the end of the month to coincide with cholesterol month.

Daiichi-Sankyo submitted that in the absence of a Daiichi-Sankyo UK Patient Organisation Agreement at the time, a Master Service Agreement (MSA) and SOW was specifically created for use with patient organisations; for the purpose of this campaign, both agreements were certified in advance in accordance with the Code. No other materials or content relating to the campaign were certified because Daiichi-Sankyo did not have any input or influence in relation to them.

Daiichi-Sankyo submitted that the patient organisation's primary objective for the campaign was optimal reach to people with potential interest in cholesterol. To achieve this, the patient organisation used key characteristics to identify its target audience for this campaign. These characteristics included gender, age (40+), interest in NHS, fitness, broad interest in health, high risk geographical areas, etc.

Coincidentally at this time, Daiichi-Sankyo UK had independently developed heatmaps which identified areas of the country where people were living with high levels of cholesterol across the UK. The heatmaps were based on publicly available data demonstrating disease burden. Primarily, the purpose of the heatmaps was to demonstrate the CVD burden and health inequalities as a call for action for policy makers. This work was undertaken by Daiichi-Sankyo UK and was non promotional in nature with no relation to Daiichi-Sankyo UK's commercial activities. The named patient organisation had undertaken its own analysis on high-risk CVD areas and also requested Daiichi-Sankyo UK's heatmaps. Daiichi-Sankyo UK had no editorial control over how, or if, it was used in relation to this campaign.

With regard to the disclaimer, Daiichi-Sankyo submitted that the campaign was funded by Daiichi-Sankyo UK, but it had no influence over the patient organisation's materials or content on websites, the target audience or how the heatmaps were to be used. These decisions were solely made by the patient organisation with no Daiichi-Sankyo involvement.

Daiichi-Sankyo denied that it had any input or influence over the 'Get clued-up on cholesterol campaign' carried out by the patient organisation.

Allegation 2

Daiichi-Sankyo submitted that the 'Let's get clued up on cholesterol' landing page was created specifically for the campaign and was a standalone piece and separate to the patient organisation's official website, hence the Daiichi-Sankyo disclaimer positioned at the top of the landing page only. There were some links to the patient organisation's official website with content that was pre-existing and separate from the campaign.

The landing page had five sections, the first section included the 'Get Clued up on Cholesterol' questionnaire, this was specifically related to the disease awareness campaign and could only be accessed via the landing page which had the Daiichi-Sankyo disclaimer. Therefore, the landing page was not accessible once the campaign had ended.

The other sections were completely separate to the disease awareness campaign and had links to the patient organisation's website which allowed the viewer to obtain further information on the patient organisation's materials if they desired. The patient organisation's website did not have the Daiichi-Sankyo disclaimer because Daiichi-Sankyo had no input or influence on the content of their website.

Allegation 3

Daiichi-Sankyo submitted that the requirement for disclosure of involvement was communicated to the patient organisation and also clearly stated in the SOW. Disclosure was only needed on the landing page and this was adhered to.

Additionally, the patient organisation used Facebook feeds to reach out to their targeted audience, which included brief and general messages on cholesterol and the campaign. These messages showed the patient organisation as the sole sponsor of the campaign as per Facebook's criteria. Daiichi-Sankyo made all the arrangements to make the sponsorship explicitly clear but in 2020 Facebook did not have the functionality to add additional sponsors, only the patient organisation could appear as a sponsor because they were the campaign

owner. However, since the campaign, Facebook had now made this functionality available for multiple sponsors. That said, all users clicking on any of the Facebook messages were taken to this landing page which had the Daiichi-Sankyo disclaimer.

Daiichi-Sankyo submitted that on the patient organisation's request, it shared the heatmaps and it was the patient organisation's decision on how they used the data. The patient organisation shared data analytics generated from the digital campaign as part of the sponsorship. Based on this, the interaction was not an arm's length grant; it was a sponsorship. The patient organisation decided what materials to create and how to use the Heat maps, and Daiichi-Sankyo had no input into how the Heat maps were used in this campaign.

Allegation 4

Daiichi-Sankyo submitted that the patient organisation disease awareness campaign was sponsored by Daiichi-Sankyo, it was not a grant.

The SOW for this campaign clearly stated declaration of involvement requirements and Daiichi-Sankyo made all the arrangements to ensure this was adhered to. As explained above, Daiichi-Sankyo had no influence or involvement in the creation of the materials used for this campaign.

Allegation 5

Daiichi-Sankyo submitted that the patient organisation had included other links to their website on the campaign landing page. 'Learn more about treatments' was one of the links which took the viewer directly to the patient organisations pre-existing website. The treatment section on this website included all of the lipid lowering treatments currently available. At the time of this campaign, bempedoic and other new treatments were mentioned but not detailed on the website since they were not available. These sections were part of the patient organisations main website and Daiichi-Sankyo had no input into any of the content in this section and this was not part of this campaign.

In summary, Daiichi-Sankyo refuted the breaches of Clauses 2, 5.1, 5.5, 8.3, 23.2, 26.1 and 26.2 of the 2021 Code in relation to the relationship with the named patient organisation and its website.

Allegation 6 – abbreviated advertisement

Daiichi-Sankyo submitted that this advertisement ran in the June, September and December issues of MIMS which was a quarterly publication. Daiichi-Sankyo considered the requirements of the Code when approving this abbreviated advertisement. However, Daiichi-Sankyo accepted that the statements should have been concise and therefore accepted a breach of Clause 13.8.

Daiichi-Sankyo subsequently requested that MIMS deleted the advertisement files from their server. In addition, Daiichi-Sankyo confirmed that this was the only abbreviated advertisement that was in use for Nilemdo/Nustendi and that no other advertisement was impacted by the complaint.

Conclusion

Daiichi-Sankyo submitted that it had taken this matter seriously, maintained high standards, and had not, in any way, brought discredit upon, or reduce confidence in, the pharmaceutical industry.

PANEL RULING

1. Disease awareness campaign and relationship with the named patient organisation

The Panel noted Daiichi-Sankyo's submission that it had sponsored the disease awareness campaign in question, 'Get clued up on cholesterol', which involved providing funding to the named patient organisation to cover digital expertise and social media costs; the patient organisation had also, according to Daiichi Sankyo, requested data from it relating to cardiovascular (CVD) disease and lipid hotspot areas across the UK ('heat maps') which was said to be non-promotional and in the public domain.

The Panel noted that there was a master services agreement (MSA) for the named patient organisation to provide services to Daiichi-Sankyo which was certified and signed by Daiichi-Sankyo in September 2020. The MSA stated that it covered all activities associated with this patient group including digital disease awareness campaigns.

The MSA set out the terms on which the patient organisation would provide services to Daiichi-Sankyo. It referred throughout to the patient organisation providing services to Daiichi-Sankyo. Section 7.1, however, referred to the relationship as a collaboration which, in the Panel's view, could be seen as inconsistent with a contract for services. Further, Section 7.1 provided that material produced as a result of the collaboration with 'the company' will be the property of 'the company' and the named patient organisation was referred to as 'the company' throughout the contract. The Panel queried whether ownership of all output materials by the patient organisation would be consistent with a contract for services.

The Panel further noted that a statement of work (SOW) for the '[named patient organisation] digital disease awareness campaign' was dated 7 July 2020 and referred to the 'commencement of the services' on 14 July 2020. The SOW stated that the patient organisation was to identify the target audience and create assets in July/August 2020. It was signed and certified by Daiichi-Sankyo in September 2020.

The objective stated in the SOW was 'to support a campaign to reach 1 million people to talk about cholesterol during [named patient organisation]'s national cholesterol month in October 2020.' Under the heading 'Services data', it stated 'Work with Daiichi Sankyo to analyse the publicly available data, cross-matching areas of the country to create a 'heat map' of areas with high CVD, illustrating geographical locations with the highest number of people at risk' and went on to list the following four services: Create a landing page on the [named patient organisation] website; create an educational knowledge test about cholesterol; create a downloadable heart healthy recipes and cholesterol lowering advice PDF; engage with National Cholesterol Month e-news. The SOW stated that the services would be completed on 31 October 2020. Section 8 of the SOW stated, *inter alia*, that '...[named patient organisation] must always declare and acknowledge sponsorship from the outset' and that the patient organisation retained full editorial control over all published materials and that Daiichi-Sankyo would not seek to influence the text of the material in a manner favourable to its own commercial interests but that this did not preclude Daiichi-Sankyo from correcting factual inaccuracies.

Sponsorship was defined in Clause 1.22 of the 2021 Code as meaning a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation. The Panel noted that sponsorship was a different activity to where a patient organisation provided a contracted service to a company as described in Clause 24. Sponsorship was not defined in the 2019 Code although examples of sponsorship were described in published cases.

The Panel considered that it was important that companies were clear about the classification of activities under the Code and that the classification should be consistently described across materials including contracts. It appeared to the Panel that Daiichi-Sankyo had not distinguished between a contracted service provided by the patient organisation to Daiichi-Sankyo versus sponsorship of the patient organisation's material and the company had used both terms within the SOW in relation to the disease awareness campaign. The term sponsorship was used in the SOW solely in relation to the Code requirement to declare details of a company's involvement in certain materials. The Panel noted that in its response to the complaint, Daiichi-Sankyo consistently described the relationship as sponsorship. The MSA consistently described the arrangement between Daiichi-Sankyo and the named patient organisation as a contract for services save in one instance described above where the arrangements were described as a collaboration. A contracted service had different requirements under the Code to that of sponsorship of patient organisation material. Importantly, a pharmaceutical company contracting a patient organisation to provide it with a service would mean that the pharmaceutical company was responsible for the activity and materials under the Code. Whether a pharmaceutical company was responsible for materials produced as a result of a sponsorship would depend on the sponsorship arrangements.

The Panel noted that companies could sponsor patient organisation material and not be responsible for its content but only if the sponsorship was arm's length. The Panel noted Daiichi-Sankyo's submission that on the patient organisation's request, Daiichi-Sankyo shared the heatmaps with the patient organisation and the patient organisation shared with Daiichi-Sankyo data analytics generated from the digital campaign which according to Daiichi-Sankyo meant that the interaction was a sponsorship. It appeared to the Panel, and acknowledged by Daiichi-Sankyo, that the arrangement was not arm's length and therefore, in the Panel's view, Daiichi-Sankyo was responsible for the content irrespective of whether the activity was classified as sponsorship of patient organisation material or the provision of contracted services.

Whilst noting with concern the inconsistent classification of the arrangements as described above, the Panel noted that the MSA and SOW set out the legal basis of the arrangements between the parties and in this regard noted that whilst the MSA predominantly referred to a contract for services, Daiichi-Sankyo's response consistently referred to sponsorship. The MSA referred to ownership of materials remaining with the patient organisation which in the Panel's view appeared to be inconsistent with a contract for services. The SOW was not sufficiently clear about the classification of the materials. In the absence of a clear and unambiguous classification in the MSA and SOW and noting the ownership of materials by the patient organisation and Daiichi-Sankyo's response on this point, the Panel decided, on balance, that the arrangements were to be considered a sponsorship which was not at arm's length and thus Daiichi-Sankyo was responsible for the content of the materials. Thus, the Panel made its rulings on that basis.

The Panel noted that the complaint was made in December 2021 and the complainant had raised clauses from the 2021 Code which came into operation on 1 July 2021. Noting the dates in the SOW, and the date of the campaign (2020), the Panel considered that the 2019 Code was the relevant Code when the agreement between the patient organisation and Daiichi-Sankyo was made, and when the campaign was launched, however, allegations made in relation to material still active after 1 July 2021 would nonetheless be covered by the 2021 Code. The Panel noted both the 2019 and 2021 Codes made a clear distinction between a patient organisation providing a service to a pharmaceutical company and a pharmaceutical company sponsoring patient organisation material. The Panel thus decided to make its rulings under the 2019 Code for all allegations whilst noting the relevant clause in the 2021 Code.

The 2019 Code was in operation when the MSA and SOW were signed and certified by Daiichi-Sankyo. Clause 8.3 in the 2021 Code was similar in certain respects to Clause 14.3 in the 2019 Code in relation to material related to working with patient organisations. Clause 27.3 of the 2019 Code stated that companies working with patient organisations must have in place a written agreement setting out exactly what had been agreed and its supplementary information required such written agreements to be certified as set out in Clause 14.3. The Panel noted that the MSA and SOW were certified in September 2020, after the date of the commencement of services (14 July 2020) referred to in the SOW and considered that the contract had not been certified when the activity in question had commenced. The Panel therefore ruled a breach of Clause 14.3 of the 2019 Code (similar to Clause 8.3 of the 2021 Code).

The Panel noted the content of the webpage accessed by the case preparation manager from the link provided by the complainant. The Panel queried Daiichi-Sankyo's submission that the 'landing page' was not accessible once the campaign had ended; the webpage in question had been accessed by the case preparation manager in December 2021. This webpage was headed 'Get Clued-Up on Cholesterol' and immediately beneath stated 'Daiichi Sankyo have assisted [patient organisation] by providing funding for this communication programme, and identification of areas of the country where people are living with high levels of cholesterol for [patient organisation] to reach out to. Daiichi Sankyo have had no input or influence over [patient organisation]'s materials used in this campaign'.

Clause 9.10 of the 2019 Code (similar to Clause 5.5 of the 2021 Code) stated *inter alia* 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 to this clause stated that the wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence. This was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party. The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset.

The Panel noted the complainant's allegation that the declaration of Daiichi-Sankyo's involvement in the campaign was missing from other webpages related to the campaign which a member of the public might access. In this regard, the Panel noted that the complainant did not identify any specific webpages, although in relation to this allegation the complainant made a general reference to all pages related to the campaign. The Panel further noted Daiichi-Sankyo's submission that the 'Let's get clued up on cholesterol' landing page was created specifically for the campaign and was a standalone piece and separate to the patient

organisation's official website, and that the 'Get Clued up on Cholesterol' questionnaire could only be accessed via the landing page which had the Daiichi-Sankyo disclaimer. The Panel did not have a copy of the questionnaire before it and did not know if the questionnaire could be downloaded as a standalone item. It was not described as downloadable in the SOW. The Panel noted that the SOW also referred to 'downloadable heart healthy recipes' and the webpage accessed by the case preparation manager which appeared to be the landing page had a section titled 'Tasty ways to manage your cholesterol' which featured links to various categories of recipes. The Panel did not have copies of these recipes. It appeared to the Panel that these recipes were likely to be what was referred to in the SOW and the subject of the complainant's allegation. The Panel considered that if the recipes or the questionnaire were downloadable and/or could be directly accessed by any other route other than the landing page, a declaration of involvement would be required on each piece of material; however, according to Daiichi-Sankyo, its declaration of involvement was only on the landing page. The Panel noted that the SOW stated that the recipes were downloadable and therefore, on the balance of probabilities, the Panel considered that there was downloadable material related to the campaign in question. The Panel, therefore, noting its decision above that the material in question was sponsored material, considered that it appeared the requirements of Clause 9.10 had not been met in relation to the downloadable recipes. A breach of Clause 9.10 of the 2019 Code was ruled (similar to Clause 5.5 of the 2021 Code).

The Panel noted, in relation to the complainant's reference to social media campaigns, that Daiichi-Sankyo submitted that the patient organisation used Facebook to reach out to the targeted audience and that these messages showed the patient organisation as the sole sponsor of the campaign as, according to Daiichi Sankyo, Facebook did not have the functionality to add additional sponsors in 2020 and therefore only the patient organisation, as campaign owner, could appear as a sponsor but all users clicking on any of the Facebook messages were taken to the landing page which had the Daiichi-Sankyo disclaimer.

The Panel noted that whilst it did not have a copy of the posts in question, Daiichi-Sankyo had submitted that there was no reference to Daiichi-Sankyo on the Facebook posts themselves and users would have to click on the messages to go to a webpage which had reference to Daiichi-Sankyo. The Panel therefore ruled a further breach of Clause 9.10 of the 2019 Code (similar to Clause 5.5 of the 2021 Code).

In relation to the allegation that all material related to the campaign required certification as Daiichi-Sankyo's involvement was not arm's length, the Panel noted its decision above that the arrangement was one of sponsorship and as it was not an arm's length sponsorship, Daiichi-Sankyo was responsible for the materials. The Panel considered that all the educational material for the public required certification (Clause 8.3 in 2021 Code was similar to Clause 14.3 of the 2019 Code). The Panel noted Daiichi-Sankyo's submission that apart from the written agreements, no other materials or content relating to the campaign were certified. The Panel therefore ruled a breach of Clause 14.3 of the 2019 Code in relation to the publicly available campaign material which had not been certified.

In relation to the allegation that the written agreement was not clear on the requirement for a declaration of involvement from the outset for all parts of the programme, the Panel noted that section 8 of the SOW stated that the named patient organisation must always declare and acknowledge sponsorship from the outset. Whilst the Panel had concerns about the SOW in general as referred to above, the Panel noted that the complainant had cited Clause 23.2 of the 2021 Code (similar to Clause 19 of the 2019 Code) which referred to donations and grants. The

Panel considered that the payment to the named patient organisation did not constitute a donation or grant and therefore the clause raised was not relevant. No breach of Clause 19.2 of the 2019 Code (similar to Clause 23.2 of the 2021 Code) was ruled in that regard.

In relation to the allegation that bempedoic acid was referred to on the treatments page, the Panel noted Daiichi-Sankyo's submission that the treatment section on the patient organisation's website included all of the lipid lowering treatments currently available at the time of the campaign; at that time, bempedoic acid and other new treatments were mentioned but not detailed on the website since they were not available. The Panel further noted Daiichi-Sankyo's submission that the treatment section was part of the patient organisation's main website and was not part of the disease awareness campaign and that Daiichi-Sankyo had no input into any of the content of the treatments section on the patient organisation's website.

Whilst the Panel considered that Daiichi-Sankyo was responsible for the content of the disease awareness programme, it was not responsible for the entire patient organisation's website which covered a number of topics. Nonetheless, the disease awareness material was hosted on the patient organisation's website and there appeared to be a link to the treatments page from the disease awareness page. The treatments page was headed 'Getting treatment' and stated, 'The most widely used medicine to lower cholesterol is a statin, but there are other medicines available too and some may only be prescribed in a specialist lipid clinic.' The page had a number of tabs which referred to, *inter alia*, statins, ezetimibe, PCSK9s, inclisiran and bempedoic acid. Next to bempedoic acid and inclisiran was the statement 'info coming soon'. The Panel noted that the Code did not prohibit disease awareness material referring to medicines. However, the relevant supplementary information to Clause 26.2 stated that restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. In this regard, the Panel noted Daiichi-Sankyo's submission that the page in question included all lipid lowering treatments available at the time of the campaign. The Panel noted that the page referred to a range of medicines by different companies. The Panel noted that reference to a company's medicine in disease awareness material was not in itself necessarily a breach of the Code and thus based on the very narrow allegation, that the material referred to bempedoic acid, the Panel ruled no breach of Clauses 26.1 and 26.2 (clauses similar in 2019 and 2021 Codes). In any event, the Panel considered that the complainant had not established on the balance of probabilities that Daiichi-Sankyo was responsible for the treatments page in question.

The Panel was concerned about the failure to correctly and consistently classify the activity in the MSA and SOW. The Panel was particularly concerned that Daiichi-Sankyo had not considered that it was responsible for the disease awareness materials given its acknowledgement that the arrangements were a sponsorship that was not at arm's length. Furthermore, the declaration of the company's involvement in the campaign was not on the Facebook posts, which were part of the written agreement. High standards had not been maintained in this regard and a breach of Clause 9.1 of the 2019 Code was ruled (similar to Clause 5.1 of the 2021 Code).

Clause 2 was a sign of particular censure and reserved for such use. Whilst the Panel had concerns about the relationship between Daiichi-Sankyo and the named patient organisation in relation to this disease awareness campaign as set out above, on balance, noting the limited material provided by the complainant and the content of such material, it did not consider that the complainant had established that Daiichi-Sankyo had brought discredit upon the industry and no breach of Clause 2 was ruled (similar in both the 2019 and 2021 Code).

2. Abbreviated advertisement

The Panel noted that the advertisement in question was certified in May 2021 as an abbreviated advertisement. The Panel noted Daiichi-Sankyo's submission that the advertisement was included in the June, September and December issues of MIMS. The Panel considered that in relation to the June 2021 advertisement, the applicable Code was the 2019 Code. The 2021 Code was the applicable Code for the September and December 2021 advertisements. As the requirements for abbreviated advertisements were similar in the 2019 and 2021 Codes, the Panel made its rulings in relation to the 2021 Code.

The Panel noted that the content of abbreviated advertisements was restricted as set in Clause 13 of the 2021 Code.

Clause 13.8 stated that abbreviated advertisements may contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine is recommended for the indication or indications given.

The Panel noted that the advertisement in question was headed 'In the struggle against elevated LDL-C, add on to bring down'. Beneath an image of a clinician and a patient there was a second claim which stated 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily Nilemdo or Nustendi'. Beneath the product logos was a third claim 'add on to take back control'. The Panel considered that the advertisement did not meet the requirements of an abbreviated advertisement and a breach of Clause 13.8 was ruled as acknowledged by Daiichi-Sankyo.

High standards had not been maintained in this regard and a breach of Clause 5.1 was ruled.

Complaint received 18 December 2021

Case completed 9 December 2022