CASE AUTH/3542/7/21

COMPLAINANT v DAIICHI-SANKYO

Advertisements in 'Guidelines in practice'

An anonymous contactable complainant who described him/herself as a health professional and later became non contactable, complained about an advertisement by Daiichi-Sankyo UK Ltd for Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) published in 'Guidelines in practice'. The complainant also raised concerns about two digital advertisements for Nilemdo and Nustendi and one for Lixiana (edoxaban).

The complainant stated that the 'Guidelines in practice' advertisement included the claim 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI.*[1,2]'. The asterisk took the reader to some small text at the bottom of the page which included information about concomitant use with simvastatin >40 mg daily being contraindicated and restrictions on the use of simvastatin 40 mg daily for certain patients; the complainant stated that such important information about maximum dosage and contraindication should not have been presented as small text at the bottom of the advertisement but as part of the main overarching claim at the top. Many patients would be taking a high dosage of simvastatin so adding Nilemdo or Nustendi without dosage adjustment, as the claim at the top read, would cause side effects and harm. The complainant alleged that the claim was not appropriate.

The complainant alleged that two Daiichi-Sankyo digital advertisements for Nilemdo and Nustendi did not mention simvastatin dosing information. The opening frame included 'add on to take back control' and the other frames had diluted messaging of 'add on to bring down'. The complainant alleged that the frames were misleading in isolation as a health professional would think to initiate Nilemdo or Nustendi in any patient taking any dosage of simvastatin without problems. Such mass advertising for black triangle products without important dosage information in prominence was concerning. The fact that footnotes had been used in the hard copy advertisement signalled that this information was to be carefully covered to perhaps exploit market share.

The complainant alleged that a digital advertisement for Lixiana (edoxaban) did not have a visible generic name.

The detailed response from Daiichi-Sankyo is given below.

The Panel considered the immediate and overall impression of the journal advertisement to a busy health professional. The Panel noted that the claim in question, 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI*', when read in isolation, was ambiguous with regard to what exactly the medicines were being added to. Whilst the Panel noted that Nilemdo and Nustendi could each be used alone as an adjunct to diet in certain patients, it considered that the advertisement in question overall appeared to be promoting the addition of

Nilemdo and Nustendi to existing lipid lowering medicines particularly given that the claim immediately beneath the claim at issue referred to LDL-C reduction depending on, *inter alia*, 'concomitant medicine'. The Panel therefore considered that the claim at issue within the context of the advertisement, when read alone without the corresponding footnote, misleadingly implied that there would be no concerns when adding Nilemdo and Nustendi to any existing lipid lowering medicine which was not so; Nilmedo and Nustendi were both contraindicated with concomitant simvastatin >40 mg daily and the important safety information within the footnote to the claim at issue, which was in much smaller font size and was not in the same visual field as the claim, might have been missed by a busy health professional. In the Panel's view, given that simvastatin was a commonly prescribed lipid lowering treatment, and given Nilemdo and Nustendi's indications as an add on treatment, the contraindication regarding concomitant use with simvastatin >40mg daily needed to be immediately apparent to health professionals in materials.

The Panel therefore considered that the claim 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI*', within the context of the advertisement, was misleading and the small footnote at the bottom of the advertisement did not negate the misleading impression given which could not be substantiated. Breaches of the Code were ruled including that high standards had not been maintained.

The Panel noted its comments and rulings above and considered that the misleading impression given by the claim at issue within the context of the advertisement had the potential to adversely affect safety in patients taking simvastatin >40mg daily, which the Panel considered was a commonly prescribed lipid lowering medicine, and a breach of Clause 2 was ruled.

Whilst the Panel considered that the first digital advertisement was ambiguous with regard to what exactly the medicines were being added to, it considered that, on balance, none of the frames, nor the advertisement overall, implied that the medicines could be added to any existing lipid-lowering regime or specifically statins or simvastatin >40mg. The Panel noted the indications of Nilemdo and Nustendi, in particular, that each could be used alone as an adjunct to diet in certain patients. Further, frame five included the only reference to other lipid lowering medicines and in that regard referred to the recommendation by NICE for bempedoic acid with ezetimibe where statins were contraindicated or not tolerated and where ezetimibe alone did not control LDL-C well enough. The Panel thus did not consider that failure to mention simvastatin dosing information within the body of the banner meant that the advertisement was misleading nor that the claims 'add on to take back control' and 'add on to bring down' in the context of the material in question were incapable of substantiation on the very narrow point alleged and, on balance, no breaches of the Code were ruled including Clause 2.

Nor did the Panel consider that, read in isolation, the frames would mislead a health professional to initiate Nilemdo or Nustendi in any patient taking any dosage of simvastatin as alleged and no breach was ruled.

The Panel noted that the second digital advertisement at issue consisted of the same seven frames to the first digital advertisement but in a different layout with the link to indications, prescribing information etc and reference to being intended for UK health

professionals being at the bottom of each frame. The Panel noted that its comments and rulings in relation to the digital advertisement above applied here and the Panel similarly ruled, on balance, no breaches of the Code including Clause 2.

Nor did the Panel consider that the complainant had established that inclusion of the footnotes in the hard copy advertisement and not the digital advertisements meant that this information was hidden to exploit market share as alleged and no breach was ruled in that regard.

The Panel noted that the Lixiana advertisement at issue consisted of four frames; each frame had, *inter alia*, a headline claim regarding Lixiana to the left and the Lixiana logo with the non-proprietary name appearing beneath it in the top right-hand corner. The Panel noted that although the non-proprietary name did not appear immediately adjacent to the brand name at its first appearance within the advertisement in question, it did appear below the brand name within the logo on each frame and, based on the complainant's very narrow allegation, that the generic name was not visible at all, the Panel ruled no breach of the Code.

The Panel did not consider that in the particular circumstances of this case Daiichi-Sankyo had failed to maintain high standards and no breach was ruled.

An anonymous contactable complainant who described him/herself as a health professional and later could not be contacted, complained about an advertisement by Daiichi-Sankyo UK Ltd for Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) (job code: BEM/21/0267, Date of preparation: April 2021) in the June 2021, Volume 24, Issue 6 hardcopy edition of 'Guidelines in practice'. In addition, the complainant raised concerns about two digital advertisements for Nilemdo and Nustendi (BEM/21/0187, Date of preparation April 2021 and BEM/21/0186, Date of preparation April 2021) and one for Lixiana (edoxaban) (EDX/21/0453, Date of preparation June 2021).

COMPLAINT

The complainant stated that on page 19 of the hard copy of 'Guidelines in practice', the Nilemdo and Nustendi advertisement included the claim – 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI.*[1,2]'. The corresponding asterisk took the reader to some small text at the bottom of the page which read '* Concomitant use with simvastatin >40 mg daily is contraindicated. When NILEMDO or NUSTENDI is coadministered with simvastatin, the simvastatin dose should be limited to 20 mg daily (or 40 mg daily for patients with severe hypercholesterolaemia and who are at high risk for cardiovascular complications, who have not achieved their treatment goals on lower doses and when the benefits were expected to outweigh the potential risks).[1,2]'. The complainant stated that such important information about maximum dosage and contraindication of simvastatin should not have been presented as small text at the bottom of the advertisement but instead as part of the main overarching claim at the top as many patients would be taking a high dosage of simvastatin for cholesterol management so adding Nilemdo or Nustendi without dosage adjustment, as the claim at the top read, would cause side effects and harm. The complainant alleged that the claim was not appropriate and was thus in breach of Clauses 5.1, 6.1, 6.2 and 2.

The complainant stated that Daiichi-Sankyo had two digital advertisements for Nilemdo and Nustendi running on the cardiovascular open-access section, (BEM/21/0187, Date of preparation April 2021) and (BEM/21/0186 and Date of preparation April 2021). The advertisements did not have any mention of simvastatin dosing information anywhere. The opening frame presented itself as 'add on to take back control' and the other frames had diluted messaging of 'add on to bring down'. The complainant alleged breaches of Clauses 5.1, 6.1, 6.2 and 2 along with a breach of Clause 14.5 as the frames were misleading in isolation as a health professional would think to initiate Nilemdo or Nustendi in any patient taking any dosage of simvastatin without problems. Such mass advertising for black triangle products without important dosage information in prominence was concerning. The fact that footnotes had been used in the hard copy advertisement signalled that this information was to be carefully covered to perhaps exploit market share.

The complainant stated that on a separate digital advertisement for Lixiana (EDX/21/0453, Date of preparation June 2021), the generic name was not visible at all, in breach of Clauses 4.3 and 5.1.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 12.3 and 14.5 of the 2021 Code.

RESPONSE

Daiichi-Sankyo UK stated that it took its obligations under the Code seriously, strove to maintain high standards and behaved responsibly and ethically at all times. Daiichi-Sankyo denied all breaches.

Allegation 1

Daiichi-Sankyo confirmed that the two digital advertisements (BEM/21/0186 and BEM/21/0187, Date of preparation April 2021) went live on 6 July 2021. The printed advertisement (BEM/21/0267, Date of preparation April 2021) was provided to 'Guidelines in practice' and used in its May, June and July issues. The advertisements were aimed at general practitioners (GPs, practice pharmacists and payers).

Daiichi-Sankyo disagreed with the allegations made by the complainant that the advertisement for Nilemdo and Nustendi in the June 2021 hard copy of 'Guidelines in practice' was 'missing important dosing information related to the use of simvastatin in combination with Nilemdo and Nustendi,' that the information about 'maximum dosage and contraindication of simvastatin included in the advertisement was presented as small text instead of as part of the main overarching claim and that the claim 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI.* [1,2]' was not appropriate.

For background and context, Daiichi-Sankyo submitted that both Nilemdo and Nustendi were licensed as treatment options that could be prescribed as add-on treatments for patients who were unable to reach LDL-C goals with their current therapies. The claim, 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI.* [1,2]' which the complainant referenced, was in fact supported wholly by the licensed indication for both products and could be fully substantiated by the summaries of product characteristics (SPCs) which were included as references in this claim.

The footnote that the complainant referred to regarding 'maximum dosage and contraindication for patients on simvastatin >40mg' was additional safety information and was not intended to, nor required, to qualify the claim. This information had been included to provide additional safety information to inform the health professional's clinical decision making prior to prescribing Nilemdo and Nustendi.

Daiichi-Sankyo disagreed with the allegation that the additional information about 'maximum dosage and contraindication of simvastatin' 'should not have been presented as small text at the bottom of the advertisement but instead as part of the main overarching claim at the top'. As outlined above, the information included in the footnote was not required to qualify the claim and was simply providing additional safety information for the health professional. This additional safety information provided as part of the footnote had been presented on the same page and in bold text in an easily readable and prominent font. Therefore, Daiichi-Sankyo believed that the location and sizing of the text was appropriate and was not required to be included in the 'main overarching claim at the top' as suggested by the complainant since this was not included to qualify a claim.

In summary, as the claim 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI. * [1,2]' was reflective of the licensed indication for both Nilemdo and Nustendi and could be fully substantiated by the SPCs of both products, it was an appropriate claim and thus not misleading. Therefore, there had been no breach of Clause 6.1 and Clause 6.2.

As the footnote regarding maximum dosage and contraindication for patients on simvastatin >40mg that accompanied the claim, 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI. * [1,2]' was not intended to, nor required, to qualify the claim, Daiichi-Sankyo believed that the location of this additional safety information regarding the maximum dosage and contraindication of simvastatin was appropriate and in a text format that was of suitable size and prominence. By including this footnote, Daiichi-Sankyo had provided further information to support health professionals to make an informed decision about these products. Furthermore, Daiichi-Sankyo UK had taken the steps to direct health professionals to refer to the SPC and the prescribing information for both products, which outlined the required information for which all health professionals should consult prior to prescribing Nilemdo or Nustendi in eligible patients.

Consequently, Daiichi-Sankyo submitted that as there had been no breach of Clauses 6.1 or 6.2, there was no evidence that high standards had not been maintained (no breach of Clause 5.1). There was no evidence that Daiichi-Sankyo UK had prejudiced patient safety and thus no breach of Clause 2.

Allegation 2

Daiichi-Sankyo disagreed with the complainant's allegations that Clauses 5.1, 6.1, 6.2, 2 and 14.5 were breached in relation to the two digital advertisements for Nilemdo and Nustendi.

The information relating to the 'simvastatin dosing information' referred to by the complainant was listed in the SPC for both Nilemdo and Nustendi respectively. It was not a requirement of the Code to include this type of information in promotional advertisements.

In addition, on each frame of the advertisement, there was a clear prominent and direct click link to the indications and prescribing information, which outlined the required information all health professionals should consult prior to prescribing Nilemdo or Nustendi. There was no requirement to place the link on every frame, however, Daiichi-Sankyo had done so to facilitate health professionals readily accessing the information.

Daiichi-Sankyo disagreed with the complainant that 'that footnotes had been used in the hard copy advertisement signalled that this information was to be carefully covered to perhaps exploit market share'. The rationale for this, as stated above, was that the information on the 'simvastatin dosing information' referred to by the complainant was listed in the SPC for both Nilemdo and Nustendi respectively and it was not a requirement to include this type of information in promotional advertisements. In addition, due to the nature of digital banner advertisements, Daiichi-Sankyo took the decision not to include this information in the banner advertisement simply due to spacing limitations. As hard copy journal advertisements had more space and allowed more information to be included, the decision was made to include this as a footnote to provide additional information for health professionals.

Taking into consideration the information outlined above, Daiichi-Sankyo did not believe that there had been a breach of Clauses 6.1, 6.2 or 14.5 respectively and disagreed that the frames were misleading in isolation. By providing a link to the prescribing information for both products on each frame of the banner advertisement, it facilitated easy access of this information by health professionals in order to make an informed decision prior to prescribing these products.

Consequently, Daiichi-Sankyo submitted that as there was no breach of Clauses 6.1, 6.2, or 14.5, there was no evidence to suggest that high standards had not been maintained (no breach of Clause 5.1). Daiichi-Sankyo took the steps to provide the required prescribing and safety information for health professionals. Therefore, there had been no breach of Clause 2.

Allegation 3

The Lixiana digital advertisement (EDX/21/0453, Date of preparation June 2021) went live in June 2021 and was directed at health professional sites including 'Guidelines in practice'.

Daiichi-Sankyo UK disagreed with the complainant's allegation that 'The generic name was not visible at all…'.

In the screenshot provided by the case preparation manager, even though the image was of low resolution, the generic name for Lixiana could still be seen.

Daiichi-Sankyo provided a high-resolution version of the advertisement which was provided to 'Guidelines in practice'; in this image, Daiichi-Sankyo submitted that the generic name was clearly visible.

In Veeva PromoMats, there was confirmation that the medical signatory reviewed the final form (copy provided) through a staging link and certified the final form as it would appear in 'Guidelines in practice'.

Daiichi-Sankyo had confirmation from the agencies that this high-resolution image was uploaded, at 72dpi and it was the exact same artwork file uploaded onto the advertisement server for 'Guidelines in practice'. There was no compression at any stage.

Daiichi-Sankyo could not control the device that the advertisement was viewed on, namely the screen quality, resolution and zoom level and had ensured that all advertisements were clear, legible and contained all mandatory information in line with the Code.

Daiichi-Sankyo submitted that as the non-proprietary name for Lixiana was easily readable and it had shown all the steps taken to ensure that the generic name was clearly visible before approving this for use. Daiichi-Sankyo denied a breach of Clause 12.3 and consequently of Clause 5.1.

Conclusion

Daiichi-Sankyo stated that it had acted in line with the requirements of the Code, maintained high standards, and had not brought discredit upon, or reduced confidence in, the industry.

PANEL RULING

Allegation 1

The Panel noted that the journal advertisement at issue (BEM/21/0267 April 2021) was headed 'In the struggle against elevated LDL-C, add on to bring back down' followed by an illustration of what appeared to be a male doctor and a female patient pulling a rope attached to cholesterol into a hole in the ground. Below this were four claims, the first being the claim at issue 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI*'. The asterisk led the reader to a footnote in small bold font at the bottom of the page which read 'Concomitant use with simvastatin >40 mg daily is contraindicated. When NILEMDO or NUSTENDI is coadministered with simvastatin, the simvastatin dose should be limited to 20 mg daily (or 40 mg daily for patients with severe hypercholesterolaemia and who are at high risk for cardiovascular complications, who have not achieved their treatment goals on lower doses and when the benefits are expected to outweigh the potential risks)'. The Panel noted the complainant's concern that many patients would be taking a high dose of simvastatin for cholesterol management and therefore the claim in question, without the information in the footnote about the maximum dose of simvastatin and the related contraindication as part of the claim in the main body of the advertisement was inappropriate and might cause harm.

The Panel noted that the second claim, which appeared immediately beneath the claim in question, read 'NILEMDO reduced LDL-C by 17-28% (placebo-corrected) at 12 weeks compared with baseline, depending on risk factors and concomitant medicine.** NUSTENDI reduced LDL-C by 38% (placebo-corrected) at 12 weeks compared with baseline.†'. In relation to this claim, readers were taken to two separate footnotes in small non bold font at the bottom of the page which read '** Placebo-corrected LDL-C reductions in pivotal NILEMDO studies: CLEAR Harmony, 18%; CLEAR Wisdom, 17%; CLEAR Serenity, 21%; CLEAR Tranquility, 28%. All p<0.001 for NILEMDO vs placebo. CLEAR Harmony and CLEAR Wisdom included patients with ASCVD, HeFH or both, taking maximally tolerated statins (which could be no statin) +/- other LLT. CLEAR Serenity included primary and secondary prevention patients with statin intolerance taking very-low dose statin, non-statin LLT, or no LLT. CLEAR Tranquility included primary and secondary prevention patients with statin intolerance taking ezetimibe with low dose, very-low dose or no statin +/- other non-statin LLT.' and '† p<0.001 for NUSTENDI vs

placebo. Study 053 included patients with ASCVD, HeFH or multiple CVD risk factors, taking maximally tolerated statin therapy (which could be no statin)'.

The third claim read 'NILEMDO and NUSTENDI were generally well tolerated in clinical studies'.

The Panel noted that the fourth claim stated 'NICE have now recommended bempedoic acid with ezetimibe for routine use in the NHS where statins are contraindicated or not tolerated, and ezetimibe alone does not control LDL-C well enough'.

Clause 6.1 stated, *inter alia*, that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

The supplementary information to Clause 6.1 stated that claims in material must be capable of standing alone as regards accuracy etc and in general should not be qualified by the use of footnotes and the like.

The Panel noted Daiichi-Sankyo's submission that both Nilemdo and Nustendi were licensed as treatment options that could be prescribed as add-on treatments for patients who were unable to reach LDL-C goals with their current therapies and that the claim at issue was supported wholly by the licensed indication for both products and could be fully substantiated by the SPCs.

In that regard, the Panel noted that just above the three footnotes described above, in non-bold font of larger size to the footnotes, the advertisement stated the indications of Nilemdo and Nustendi as follows:

> 'NILEMDO is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid-lowering therapies (LLTs) in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin; alone or in combination with other LLTs in patients who are statin-intolerant, or for whom a statin is contraindicated.
>
> NUSTENDI® is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe; alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone; in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.'

The Panel noted, however, that Section 4.1 'Therapeutic indications' of the Nilemdo and Nustendi SPCs both referred the reader to Sections 4.2 (posology and method of administration), 4.3 (contraindications) and 4.4 (special warnings and precautions for use) when referring to the use of each medicine in combination with a statin.

Section 4.2 of the Nustendi and Nilemdo SPC referred to concomitant simvastatin therapy and stated that when coadministered with simvastatin, the simvastatin dose should be limited to 20mg daily (or 40mg daily for patients with severe hypercholesterolaemia and high risk for

cardiovascular complications, who have not achieved their treatment goals on lower doses and when the benefits are expected to outweigh the potential risks) (see Sections 4.4 and 4.5).

Section 4.3 of both SPCs listed concomitant use with simvastatin >40 mg daily as a contraindication and referred readers to see Sections 4.2, 4.4 and 4.5 and Section 4.4 referred to the potential risk of myopathy with concomitant use of statins.

The Panel was concerned to note that the indications given in the advertisement did not refer to the relevant sections of the products' SPCs in relation to their use with statins and in particular simvastatin.

The Panel considered the immediate and overall impression of the advertisement to a busy health professional. The Panel noted that the claim in question, 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI*', when read in isolation, was ambiguous with regard to what exactly the medicines were being added to. Whilst the Panel noted that Nilemdo and Nustendi could each be used alone as an adjunct to diet in certain patients, it considered that the advertisement in question overall appeared to be promoting the addition of Nilemdo and Nustendi to existing lipid lowering medicines particularly given that the claim immediately beneath the claim at issue referred to LDL-C reduction depending on, *inter alia*, 'concomitant medicine'. The Panel therefore considered that the claim at issue within the context of the advertisement, when read alone without the corresponding footnote, misleadingly implied that there would be no concerns when adding Nilemdo and Nustendi to any existing lipid lowering medicine which was not so; Nilmedo and Nustendi were both contraindicated with concomitant simvastatin >40 mg daily and the important safety information within the footnote to the claim at issue, which was in much smaller font size and was not in the same visual field as the claim, might have been missed by a busy health professional. In the Panel's view, given that simvastatin was a commonly prescribed lipid lowering treatment, and given Nilemdo and Nustendi's therapeutic indications as an add on treatment, the contraindication regarding concomitant use with simvastatin >40mg daily needed to be immediately apparent to health professionals in materials promoting the addition of Nilmedo or Nustendi to existing lipid lowering medicines.

The Panel therefore considered that the claim 'When you and your patients are fighting to take back cholesterol control, add on oral, once-daily NILEMDO or NUSTENDI*', within the context of the advertisement, was misleading and the small footnote at the bottom of the advertisement did not negate the misleading impression given and a breach of Clause 6.1 of the 2021 Code was ruled. The Panel considered that the misleading impression could not be substantiated, and a breach of Clause 6.2 was ruled. The Panel considered that high standards had not been maintained and a breach of Clause 5.1 was ruled.

The Panel noted that the supplementary information to Clause 2 gave examples of activities that were likely to be in breach of that clause which included prejudicing patient safety. The Panel noted its comments and rulings above and considered that the misleading impression given by the claim at issue within the context of the advertisement had the potential to adversely affect safety in patients taking simvastatin >40mg daily, which the Panel considered was a commonly prescribed lipid lowering medicine, and a breach of Clause 2 was ruled.

<u>Allegation 2</u>

The Panel noted that the first digital banner advertisement (ref BEM/21/0186) consisted of seven frames. The first frame included the Nilemdo and Nustendi logos including the products generic names with the strapline 'Add on to take back control' beneath them. An illustration of what appeared to be a female doctor and a male patient pulling a rope attached to cholesterol into a hole in the ground appeared on frames two to six. The second frame stated, 'Are you and your patients fighting to take back cholesterol control?'. The third frame stated, 'Add on oral, once-daily Nilemdo or Nustendi'. The fourth frame stated, 'In the struggle against elevated LDL-C, add on to bring down'. The fifth frame stated, 'NICE have now recommended bempedoic acid with ezetimibe for routine use in the NHS where statins are contraindicated or not tolerated, and ezetimibe alone does not control LDL-C well enough'. The sixth frame stated, 'For more information, visit Nilemdo-Nustendi.co.uk'. The final seventh frame was had no content other than the header which had appeared on all seven frames which stated 'Intended for UK health professionals only' in the top left-hand corner, gave the job bag code and date and invited readers to click a link in the top right-hand corner for, *inter alia*, indications and prescribing information.

Whilst the Panel considered that the advertisement was ambiguous with regard to what exactly the medicines were being added to, it considered that, on balance, none of the frames, nor the advertisement overall, implied that the medicines could be added to any existing lipid-lowering regime or specifically statins or simvastatin >40mg. The Panel noted the indications of Nilemdo and Nustendi, in particular, that each could be used alone as an adjunct to diet in certain patients. Further, frame five included the only reference to other lipid lowering medicines and in that regard referred to the recommendation by NICE for bempedoic acid with ezetimibe where statins were contraindicated or not tolerated and where ezetimibe alone did not control LDL-C well enough. The Panel thus did not consider that failure to mention simvastatin dosing information within the body of the banner meant that the advertisement was misleading nor that the claims 'add on to take back control' and 'add on to bring down' in the context of the material in question were incapable of substantiation on the very narrow point alleged and, on balance, no breach of Clauses 6.1 and 6.2 of the 2021 Code were ruled in that regard. The Panel consequently ruled no breach of Clauses 5.1 and 2.

Nor did the Panel consider that, read in isolation, the frames would mislead a health professional to initiate Nilemdo or Nustendi in any patient taking any dosage of simvastatin as alleged and no breach of Clause 14.5 of the 2021 Code was ruled.

The Panel noted that the second digital advertisement at issue (ref BEM/21/087) consisted of the same seven frames but in a different layout with the link to indications, prescribing information etc and reference to being intended for UK health professionals being at the bottom of each frame. The Panel noted that its comments and rulings in relation to the digital advertisement above applied here and the Panel similarly ruled, on balance, no breach of Clauses 6.1, 6.2, 5.1, 2 and 14.5 of the 2021 Code in relation to this second digital advertisement.

Nor did the Panel consider that the complainant had established that inclusion of the footnotes in the hard copy advertisement and not the digital advertisements meant that this information was hidden to exploit market share as alleged and no breach of Clause 5.1 was ruled in that regard.

Allegation 3

The Panel noted that Clause 12.3 of the 2021 Code required that the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupied a total area no less than that taken up by the brand name. The Panel noted that for electronic advertisements, the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 12.3, must appear immediately adjacent to the brand name at its first appearance in a size such that the information is readily readable.

The Panel noted that the advertisement at issue (ref EDX/21/0453) consisted of four frames; each frame had, *inter alia*, a headline claim regarding Lixiana to the left and the Lixiana logo with the non-proprietary name appearing beneath it in the top right-hand corner. The Panel noted that although the non-proprietary name did not appear immediately adjacent to the brand name at its first appearance within the advertisement in question, it did appear below the brand name within the logo on each frame and, based on the complainant's very narrow allegation, that the generic name was not visible at all, the Panel ruled no breach of Clause 12.3 of the 2021 Code.

The Panel did not consider that in the particular circumstances of this case Daiichi-Sankyo had failed to maintain high standards and no breach of Clause 5.1 was ruled.

* * * * *

During its consideration of this case, the Panel was concerned to note that the non-proprietary name did not appear immediately adjacent to the first appearance of Lixiana within the advertisement as required by Clause 12.3. The Panel requested that Daiichi-Sankyo be advised of its concerns.

Complaint received **19 July 2021**

Case completed **15 May 2022**